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NORTHERN CALIFORNIA AND
BAY GUARDIAN

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

JCS

CV 11 3949

AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA and BAY GUARDIAN,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Defendant.

Case No. _____

COMPLAINT FOR INJUNCTIVE RELIEF UNDER THE FREEDOM OF INFORMATION ACT, 5 U.S.C. § 552

INTRODUCTION

1. This is an action to enforce the Freedom of Information Act, 5 U.S.C. § 552, ("FOIA"), under which the public is presumptively entitled to request and receive in their entirety documents held by government agencies. On January 4, 2011, Plaintiffs the American Civil Liberties Union of Northern California ("ACLU-NC") and the *San Francisco Bay Guardian* ("*Bay Guardian*") submitted a FOIA request seeking from Defendant, the U.S. Food and Drug Administration ("FDA"), records pertaining to the federal government's role in overseeing, or failing to oversee, state prisons' procurements of lethal injection drugs. These drugs are subject to regulation, including import restrictions, by the FDA. In response, FDA has failed to conduct an adequate search, withheld certain entire documents in its possession that bear upon Plaintiffs' request, and released others with redactions so heavy as to eviscerate them of meaningful content. After months of letters and phone conversations, and the filing of administrative appeals, FDA still refuses to turn over the withheld material or make a meaningful effort to justify itself under statutory exemptions. FDA is in violation of FOIA, and is suppressing information that pertains to an urgent matter of great public concern.

2. Thirty states, including California, employ a three-drug protocol for executing condemned inmates by lethal injection. This protocol uses a single painkiller, sodium thiopental, in conjunction with pancuronium bromide, a paralytic agent, and potassium chloride, a salt which induces cardiac arrest when injected. Potassium chloride causes extreme pain as it stops the heart. Pancuronium bromide paralyzes all voluntary muscles and prevents any visible movement; it induces such total paralysis that even a person in extreme distress is rendered completely motionless. Prevention of an excruciatingly but invisibly painful death thus depends on the proper administration of sodium thiopental of sufficient quality and dosage.

3. Last year, the only domestic supplier of sodium thiopental encountered production problems and a nationwide shortage of the drug ensued. Prisons began to seek the drug from other sources. However, the FDA has not approved any foreign source for the importation of sodium thiopental. Information requests and litigation have revealed the identities of some of these sources, which were plainly not suppliers of first resort, and often appear to lack expertise.

For example, domestic and foreign media have reported extensively on British supplier "Dream Pharma Ltd.," which operates in a country where capital punishment is outlawed and which shares an office with a driving school. Its owner, Mehdi Alavi, claims to have had "no idea" why a prison in Arizona would want a shipment of sodium thiopental, pancuronium bromide, and potassium chloride. These media reports have heightened concerns as to the quality of these imported drugs. The efficacy of sodium thiopental, the only drug in the three-drug lethal injection protocol which can lessen pain, depends upon factors such as its age, its purity, and how it has been stored. If executioners use sodium thiopental that is deficient in any of these respects, there is an increased risk of cruel and excruciatingly painful death.

4. Plaintiffs are also concerned that prisons are violating foreign and domestic laws by purchasing drugs from unlicensed suppliers and in countries with laws that forbid their sale for capital punishment. The public has a basic interest in understanding the role of the federal government in overseeing the acquisition and use of federally-regulated drugs by states for the purpose of executing inmates by lethal injection. The public also has a right to know how the government spends public funds. The public's need to know is especially keen where state governments may be spending public money to circumvent or violate the law.

5. The documents Plaintiffs seek regarding the procurement of lethal injection drugs go to the heart of FOIA's statutory aims of promoting open government, preventing the entrenchment of secret governmental practices, and permitting public scrutiny of federal and state governmental action. Plaintiffs seek basic information regarding the price, quantity, source, destination, and transportation of the drugs. Information about quantity, source, and destination could, for example, help the public determine which states may possess drugs of substandard quality. Similarly, more information about the transportation process could indicate whether or not drugs like sodium thiopental have been properly stored so as to prevent premature degradation. Pricing data would inform the public how officials are spending taxpayer funds.

6. FDA's response to Plaintiffs' FOIA request does not fulfill its obligations under the law. Far from applying exemptions sparingly, as courts have held FOIA requires, FDA has redacted from documents information that cannot plausibly fall under any exemption. FDA has

also failed to conduct an adequate search for relevant documents. Plaintiffs have filed multiple administrative appeals, citing to specific judicial opinions defining the scope of FOIA exemptions, but FDA has yet to make any substantive reply.

7. Having exhausted their administrative remedies, Plaintiffs now respectfully petition the Court to compel production of these documents without further delay.

PARTIES

8. Plaintiff American Civil Liberties Union of Northern California, a nonprofit organization established under the laws of the state of California and headquartered in San Francisco, California, is an affiliate of the American Civil Liberties Union, a national, non-profit, non-partisan organization. Its mission is to protect civil liberties from government incursions, safeguard basic constitutional rights, and advocate for open government. ACLU-NC has approximately 50,000 members, and operates a communications department which disseminates information to the public through newsletters, its website, and other publications.

9. Plaintiff *Bay Guardian* is a corporation organized under the laws of the state of California and headquartered in San Francisco, California. It is a locally-owned, independent newspaper of general circulation, published continuously since 1966, and has the largest circulation of any newsweekly in Northern California, with an audited weekly distribution of approximately 100,000. As a newspaper, its primary activity is publishing or otherwise disseminating information to the public. *Bay Guardian* has published extensively on state efforts to acquire sodium thiopental for use in executions, and is prepared to publish appropriate articles concerning this subject based on information sought by the FOIA request at issue here. In 2011, *Bay Guardian* received the California Newspaper Publishers Association's General Excellence award for a weekly newspaper.

10. Defendant Food and Drug Administration is an agency within the United States Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. § 552(f). It is headquartered in Maryland and operates a San Francisco field office.

JURISDICTION

11. This Court has subject matter jurisdiction over this action and personal jurisdiction

over the parties pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(C)(i). Because this action arises under FOIA against an agency of the United States, this Court also has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346.

VENUE AND INTRADISTRICT ASSIGNMENT

12. Venue is proper in this district pursuant to 5 U.S.C. §552(a)(4)(B) and 28 U.S.C. §§ 1391(e) and §1402.

13. Pursuant to Local Rule 3-2(c) and (d), assignment to the San Francisco division is proper because a substantial portion of the events giving rise to this action occurred in this district and division, and because both Plaintiffs are headquartered in San Francisco.

FACTUAL BACKGROUND

14. Many states use sodium thiopental as part of a process to execute condemned prisoners. States that use the three-drug protocol administer sodium thiopental first, to induce unconsciousness and render the inmate insensitive to pain, before injecting pancuronium bromide and potassium chloride, which respectively paralyze the inmate's muscles and induce cardiac arrest. The state of Washington uses sodium thiopental alone to carry out executions.

15. Of these three lethal injection drugs, only sodium thiopental acts to alleviate pain. Indeed, the other two drugs each inflict pain. *See Lethal Injection Web-Based Clearinghouse*, http://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/QA/9.html (last visited July 21, 2011). Pancuronium bromide induces complete paralysis, preventing any visible movement. This paralysis conceals any signs that an inmate has regained consciousness and is experiencing pain, even the extreme pain caused by potassium chloride.

16. The efficacy of a given quantity of sodium thiopental diminishes with time; the FDA-approved Hospira version of the drug has a shelf life of only two years. Its efficacy also depends upon factors such as its purity and whether it has been properly stored.

Nationwide Shortage of Sodium Thiopental

17. On information and belief, in May 2010, Hospira, Inc. ("Hospira"), the only domestic supplier of sodium thiopental approved by FDA, stopped selling sodium thiopental. The resulting shortage of sodium thiopental led some states to postpone executions, or to rush to

conduct them before the expiration dates of their remaining supplies. As the shortage began to impact executions, attorneys, community members, and journalists began expressing concern as to how state corrections officials would obtain sodium thiopental, whether government officials would violate any state or federal laws in their efforts to obtain the drug, and what other steps officials might take in order to proceed with executions.

18. News media reported extensively on the scheduled execution of Albert Brown in California, set for 9:00 PM on September 30, 2010 using sodium thiopental that was to expire on October 1. This execution was to be the first following a four-year moratorium on executions that a federal judge had imposed, citing concerns about California's lethal injection procedures. *See generally Morales v. Tilton*, 465 F. Supp. 2d 972 (N.D. Cal. 2006). On August 30, 2010, a mere month before the sodium thiopental's expiration, Judge Roger Luebs set Mr. Brown's execution date. The execution was delayed beyond October 1 due to litigation relating to the re-implementation of the death penalty. On appeal, the United States Court of Appeals for the Ninth Circuit remarked that "it is incredible to think that the deliberative process might be driven by the expiration date of the execution drug." *Morales v. Cate*, 623 F.3d 828, 829 (9th Cir. 2010).

Extraordinary Measures by States to Acquire Sodium Thiopental

19. On information and belief, at the end of September 2010, the state of Arizona acquired a new supply of sodium thiopental. The state eventually revealed that it had imported sodium thiopental from the United Kingdom, but did not explain how it had imported the drug, given that federal law prohibits importation of controlled substances from sources that are not registered with the FDA. *See* 21 U.S.C. §§ 360(i) (registration requirement) and 331(p) (unlawful to fail to register); *see also* 21 C.F.R. §§ 1312.11(b), (c), 1312.18(c)(4). However, there is no federally-approved source for the importation of sodium thiopental. Although Arizona carried out two executions using sodium thiopental imported from the United Kingdom, the Arizona Supreme Court later delayed another execution due to questions about the drug's origin and efficacy, which had become the focus of an intense legal battle with extensive media coverage.

20. Similarly, *The Bay Guardian* has reported that on October 6, 2010, the California

Department of Corrections and Rehabilitation ("CDCR") disclosed in a court filing that it too had recently obtained 12 grams of sodium thiopental, with a 2014 expiration date, despite the nationwide shortage. The CDCR did not disclose the source of the drug or explain how it came into possession of the substance. Various media outlets have reported that the last supply of sodium thiopental produced by Hospira has a 2011 expiration date. Thus, on information and belief, the sodium thiopental in the CDCR's possession could not have been manufactured domestically.

21. On October 7, 2010, Plaintiff ACLU-NC submitted to the CDCR a request for records under the California Public Records Act, seeking documents pertaining to the CDCR's acquisitions of sodium thiopental. After the CDCR failed to deliver these documents, Plaintiff ACLU-NC brought suit on November 17, 2010 in the California Superior Court for the County of San Francisco. On December 8, 2010, following an initial hearing, the CDCR delivered a set of documents to Plaintiff ACLU-NC. These documents revealed that California corrections officials had gone to great lengths in their search for the drug, including attempting initially to import it from Pakistan and exchanging lethal injection drugs with Arizona. (California provided pancuronium bromide in exchange for imported sodium thiopental obtained by Arizona). The records also revealed that Arizona corrections officials informed their California counterparts that they had imported sodium thiopental from the United Kingdom and provided a roadmap for doing so, and that California corrections officials then followed Arizona's lead and also imported the drug directly from the United Kingdom.

22. CDCR revealed to selected journalists in December 2010 that it had ordered 521 grams of sodium thiopental manufactured by a company in the United Kingdom. CDCR stated that it had paid more than $36,000 to acquire the drug, and that the controlled substance had arrived in the United States and was awaiting inspection by the FDA.

23. Plaintiff ACLU-NC posted the records produced by CDCR to its website promptly upon receipt. Since posting, the web page has had more than 2,000 unique visitors and has been viewed more than 3,000 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website. The records are available at

http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response_to_aclu_public_records_act_request.shtml.

24. The records disclosed by CDCR raise questions about the conduct of state officials in importing a controlled substance from abroad and exchanging controlled substances with another state, and in particular, whether California corrections officials have complied with the Controlled Substances Act and the Food, Drug, and Cosmetics Act. See, *e.g.*, 21 U.S.C. §331(a), (c) (unlawful to introduce, deliver for introduction, or receive in interstate commerce adulterated or misbranded drugs); 21 U.S.C. §355(a) (unlawful to introduce or deliver for introduction new drug); 21 U.S.C. § 829 (unlawful for person other than physician to dispense Schedule III substance without prescription); 21 C.F.R. § 1312.11(b) (requirement of authorization to import); 21 C.F.R. §314.410(a) (regulations governing import); 21 C.F.R. § 207.40(b) ("No drug may be imported or offered for import into the United States unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment").

25. Critically, the records sought by Plaintiffs in their FOIA requests raise questions about the role of federal officials in overseeing – or failing to oversee – the importation process.

26. Records produced through other FOIA requests and state public record act requests across the country have now revealed that eight states imported sodium thiopental from a distributor in the United Kingdom, Dream Pharma, in 2010 and 2011. Dream Pharma is not an FDA-approved source of sodium thiopental; indeed, as noted above there is no approved foreign source for the importation of sodium thiopental. In addition to California and Arizona, Alabama, Arkansas, Georgia, Kentucky, South Carolina, and Tennessee have also imported controlled substances from Dream Pharma. A private company in the state of Georgia also provided some of the imported sodium thiopental to prison officials in Kentucky. Two other states, Nebraska and South Dakota, imported a controlled substance purporting to be sodium thiopental from a company in India.

27. These procurement methods have generated public outcry, legal challenges, and media attention in the United Kingdom, United States, and elsewhere. Following disclosure that

states in the United States were acquiring execution drugs from sources in the United Kingdom, the government of the United Kingdom imposed new restrictions preventing the export of all controlled substances for purposes of execution.

FDA Has Denied Plaintiffs' Lawful Request Under FOIA

28. On January 4, 2011, Plaintiffs ACLU-NC and *The Bay Guardian* submitted a FOIA request to FDA. This request sought documents relating to state governments' acquisitions of sodium thiopental, pancuronium bromide, and potassium chloride for the purpose of execution. A copy of Plaintiffs' January 4, 2011 FOIA request, without attachments, is attached hereto as Exhibit A.

29. FDA responded to the Plaintiffs' January 4, 2011 FOIA request with a series of document productions dated January 19, February 8, March 21, March 31, April 20, and May 27, 2011.

30. FDA has failed to conduct an adequate search for relevant records. It has also improperly withheld documents and portions of documents sought by Plaintiffs' FOIA request. Specific examples are discussed below.

31. Plaintiffs appealed FDA's withholdings and redactions on February 15, 2011 (concerning documents from FDA's New Orleans office), April 29, 2011 (concerning documents from FDA's Los Angeles office), May 10, 2011 (concerning additional New Orleans documents), and July 8, 2011 (concerning additional Los Angeles documents). These appeals highlighted specific examples of inadequate search, improper withholdings and redactions, and cited case law to support these propositions. Copies of these appeals are attached as Exhibit B. FDA has not responded substantively to any of these appeals, and the statutorily-allotted 20 working days for it to do so have elapsed. Plaintiffs have thus exhausted their administrative remedies.

Inadequate Search for Records

32. FDA has failed to exhaustively search for and disclose to Plaintiffs all relevant public records in its possession, withholding entire responsive documents as a result.

33. For example, FDA has failed to produce relevant records whose existence was established in publicly-available court documents. In *Beaty v. FDA*, FDA submitted 70 pages of

administrative records to the District of Columbia District Court.

34. These records include various FDA emails regarding the importation of sodium thiopental, communications with the media and the British government regarding the use of sodium thiopental in the U.S., a November 10, 2010 letter to the FDA from the Arizona Department of Corrections regarding one of its shipments of imported execution drugs, and a December 29, 2010 document entitled "Sodium Thiopental Statement, Key Messages."

35. For example, as detailed in Plaintiffs' May 10, 2011 administrative appeal, the December 29, 2010 document entitled "Sodium Thiopental Statement, Key Messages" references a "longstanding policy" relating to imported sodium thiopental and a review of related procedures. Plaintiffs' FOIA requests specifically sought documents related to any such policy and review, yet none have been produced.

36. Additionally, the contents of the documents Plaintiffs have procured through records requests to other agencies indicate that FDA possesses responsive records that it has not produced nor identified as exempt. For example, a November 11, 2010 email that the Drug Enforcement Administration ("DEA") produced to Plaintiffs shows an attached file named "revised lethal injection memo 11 10 10.docx" that DEA identifies as an FDA document, yet FDA has produced no such document. The DEA email describes the document as pertaining to the importation of sodium thiopental for the purpose of lethal injection, which falls squarely within Plaintiffs' FOIA requests.

37. Furthermore, FDA has failed to produce responsive information about the Dream Pharma shipments. On information and belief, each shipment from Dream Pharma should have the following: Notice of FDA Action (possibly several such notices), Entry/Immediate Delivery Form, Invoice, Manifest, Airbill, DEA Registration Form, and one or more FDA OASIS database entries. OASIS signifies "Operational and Administrative System for Import Support," and on information and belief, is the database in which FDA stores information on the inspection and processing of potential imports.

38. As detailed in Plaintiffs' May 10, 2011 administrative appeal, FDA has produced only some of these documents for each shipment of drugs.

39. These withholdings violate FOIA and demonstrate that FDA has not conducted an adequate search for records.

Withheld Price, Quantity, Source, and Destination Information

40. FDA has withheld documents and portions of documents that relate to the price and quantity of drugs purchased by state officials. For example, FDA has redacted the quantity and price columns of many invoices (and other documents which bear this information).

41. FDA has also withheld documents and portions of documents that relate to the sources and destinations of drugs purchased by state officials, such as the names of importers, transportation information such as flight numbers, and receiving party addresses.

42. For example, in the documents delivered to Plaintiffs on April 11, 2011, a Customs Service form titled "ENTRY/IMMEDIATE DELIVERY" and dated June 28, 2010 is redacted in fourteen places. FDA has redacted the destination ("ultimate consignee name"), the importer ("importer of record name"), the flight numbers, the applicant's signature, and other information.

43. FDA has principally cited 5 U.S.C. § 552(b)(4) ("Exemption Four") to justify these withholdings. Exemption Four allows government agencies in receipt of a FOIA request to withhold "trade secrets" and "privileged or confidential" information. The drafters included this exemption to encourage voluntary reporting of sensitive commercial information to regulators.

44. The quantity, price, source, and destination of goods are neither "trade secrets" nor "privileged or confidential" information. Exemption Four is not, therefore, a valid basis for FDA to withhold this information. FDA has not explained how this information could possibly constitute material covered by Exemption Four. In their administrative appeals, Plaintiffs explained to FDA that courts have in fact ruled to the contrary. FDA also cites 5 U.S.C. § 552(b)(6) ("Exemption Six"), which covers "personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

45. In the "ENTRY/IMMEDIATE DELIVERY" form cited above, for instance, the "signature of applicant" field is redacted with a citation to Exemption 6.

46. An applicant's signature on a customs form is not a personnel or medical record or

similar file the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

47. Exemption Six does not cover an applicant's signature. As with Exemption Four, FDA has asserted Exemption Six to justify redacting data which courts have expressly held is not within its scope.

48. FDA's improper and unjustified redactions of price, quantity, source and destination information violate FOIA.

Withheld Email Communications

49. FDA has redacted the entire body text of emails. For example, in the documents from the delivery dated March 31, 2011, FDA has redacted the entire text of a September 29, 2010 email from Huascar Batista, described in his signature block as "Imports & Exports Compliance Team Leader" for the FDA. In that same delivery, FDA has also redacted other emails, such as the September 29, 2010 email from John E. Verbeten.

50. FDA has cited 5 U.S.C. § 552(b)(5) ("Exemption Five") to justify these redactions.

51. Exemption Five allows government agencies in receipt of a FOIA request to withhold inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. It does not apply to final opinions or dispositions of an issue. Based upon the email response of Consumer Safety Officer David Thomas to Huascar Batista's September 29, 2010 email, which includes a statement by Thomas that, "[t]o confirm, CDER [Batista's division] is not objecting to the release of *the above entry of 3 pharmaceuticals* from U.K.", it appears that Batista's email contains a final opinion or disposition as to whether or not CDER objects to the release of "3 pharmaceuticals from U.K.," placing these redactions beyond the plausible scope of Exemption Five.

52. FDA's redaction of the body of these emails, and its failure to justify these redactions on administrative appeal, violates FOIA.

Withheld Arizona Supreme Court Case Name

53. In a September 24, 2010 letter from Charles L. Ryan to David Thomas, included in the March 31, 2011 set of documents, FDA has redacted a party name in a case cited for the

proposition that "this shipment of drugs was warranted by the Arizona Supreme Court," leaving the citation in the form of "State v _____."

54. FDA has cited Exemption 6 to justify this redaction. Exemption 6 covers "personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

55. The name of a party in a case before the Arizona Supreme Court is not a personnel or medical record or similar file the disclosure of which would constitute an invasion of personal privacy. FDA has not explained how the party's name would implicate such personal privacy concerns.

56. FDA's redaction of the party's name thus violates FOIA.

Inconsistencies and Defects in Withholdings of Documents

57. FDA's responses to Plaintiffs' FOIA request are generally defective and inconsistent. FDA has frequently failed to provide the FOIA-mandated written explanations for its withholdings of documents and portions of documents. This general deficiency demonstrates that FDA's undisclosed rationales are improper.

58. For example, in the April 11, 2011 documents, FDA relies on Exemption Six and 5 U.S.C. § 552(b)(7)(C) ("Exemption 7C") interchangeably in redacting signatures and other identifying information. The use of different exemptions for the same or substantially similar information suggests that FDA itself is not sure which exemption applies, or why.

59. FDA also applies different exemptions and redactions to the same, or closely analogous, information in the April 11 documents. In some cases, information is redacted in one place and left unredacted in another. FOIA requires that information be redacted or withheld only where the agency firmly believes the information to be exempt under a specific exemption. Haphazard redaction undermines confidence that FDA has followed this principle.

60. For example, in an email from John McAuliffe to Christopher Boulmay dated November 30, 2010, FDA cites Exemption Six to redact the name of a FedEx contact person. Only a few pages earlier, in another copy of the same email, this person's name is left unredacted.

61. Other examples are found in the Dream Pharma invoices. In some invoices, the

receiving party, delivery address, and total cost of the shipment are redacted under Exemption Four, while in other invoices all of this information is disclosed.

62. At times, the FDA has labeled redactions with the text "NEC," which is not a FOIA exemption subsection and is without obvious meaning. For example, the set of documents delivered to ACLU-NC on February 8, 2011 includes a letter dated September 24, 2010, which replaces FDA's DEA registration number with the notation "NEC"; in a copy delivered on March 31, 2011, that number is replaced with a citation to 5 U.S.C. § 552(b)(7)(E) ("Exemption 7E") .

Other Withheld Information

63. FDA's redactions and withholdings are extensive, and this complaint does not purport to review them all in detail.

64. Plaintiffs allege that all documents and portions of documents responsive to their FOIA request and withheld by FDA ought not to have been withheld, and that FOIA does not permit FDA to withhold such information.

65. Plaintiffs further allege that FDA has violated FOIA by failing to provide sufficient written explanation to justify its withholding of documents.

FIRST CLAIM FOR RELIEF

Violation of Freedom of Information Act For Failure to Conduct an Adequate Search and for Wrongful Withholding Of Agency Records

66. Plaintiffs incorporate paragraphs 1 through 65 above as if fully set forth herein.

67. FDA has failed to conduct an adequate search for records, has wrongfully withheld agency records requested by Plaintiffs under FOIA, and has failed to comply with the statutory timeline for the processing of FOIA requests.

68. Plaintiffs have exhausted the applicable administrative remedies with respect to FDA's failure to search and its wrongful withholding and redaction of the requested documents.

69. Plaintiffs are entitled to injunctive relief with respect to the release and disclosure of the requested documents because FDA continues to improperly withhold agency records in violation of FOIA. Plaintiffs will suffer irreparable injury from, and have no adequate legal remedy for, FDA's illegal withholding of documents pertaining to the subjects of Plaintiffs'

FOIA request.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays that this Court:

A. Order FDA to make available immediately the requested records in their entirety;

B. Enter a preliminary and permanent injunction against FDA ordering the relief requested herein;

C. Declare that FDA's failure to search for and disclose the records requested by Plaintiffs is unlawful;

D. Award Plaintiffs their litigation costs and reasonable attorneys' fees incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E);

E. Grant such other relief as the Court may deem just and proper.

Dated: 8/11/2011

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EXHIBIT A

ACLU
AMERICAN CIVIL LIBERTIES UNION of

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

January 4, 2011

Via Certified Mail, Return Receipt Requested

U.S. Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

Re: Request Under Freedom of Information Act—Expedited Processing

Dear FOIA Officer:

The American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) submit this expedited Freedom of Information Act (FOIA) request for records in the possession of the U.S. Food and Drug Administration (FDA) pertaining to the acquisition of controlled substances by state officials in California, Arizona, and other states for the purpose of carrying out executions of condemned prisoners by lethal injection. The ACLU-NC and the *Guardian* submit this request pursuant to the FOIA, 5 U.S.C. § 552, implementing regulations 21 C.F.R. 20.40 et. seq., 28 C.F.R. § 16.1 et. seq., and any other applicable regulations.

Records recently revealed by the California Department of Corrections (CDCR) indicate that the states of California, Arizona and Arkansas have imported controlled substances to be used in executions. These records reveal that these states were in direct communication with the FDA during 2010 regarding the importation of controlled substances, the procurement of controlled substances generally, and the requirements for transferring controlled substances between state corrections departments. The records disclosed by state officials raise serious questions about whether all applicable state and federal laws have been followed in the acquisition of controlled substances for the purpose of execution. The issue has generated widespread and exceptional media coverage, with 139 stories published in the last six months. Requesters are primarily engaged in disseminating information and there is a demonstrated urgency to inform the public concerning federal government activity.

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I. Requested Records

We seek disclosure of agency records[1] in your[2] possession that fall within the following categories:

1. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

2. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the transfer between states of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

3. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

4. Records created since January 1, 2010, of internal communications within the FDA regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

5. Records created since January 1, 2010, of communications between any person at the FDA and any person outside the United States, including any official, employee or agent of any foreign government, regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

6. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of the U.S. Drug Enforcement Administration regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

7. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of U.S. Customs and Border Protection regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

[1] The term "records" as used herein includes all records or communications preserved in written or electronic form, including but not limited to: correspondence, documents, data, videotapes, audio tapes, emails, faxes, files, guidance, guidelines, evaluations, instructions, analyses, memoranda, agreements, notes, orders, policies, procedures, protocols, reports, rules, training materials, other manuals, or studies.

[2] Requestors seek records in the possession or control of the FDA office in Washington, D.C. and any field offices.

8. Records created since January 1, 2010, of communications between any person at the FDA and any private individual regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

9. Records created since January 1, 2010, regarding any actual importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

10. Records created since January 1, 2010, regarding any actual transfer of sodium thiopental, pancuronium bromide, and/or potassium chloride between state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

11. Records created since January 1, 2010, regarding any actual purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

12. Any policies, procedures, manuals, internal memorandum or other records regarding FDA procedures, policies, regulations or rules for the importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

II. Request for Expedited Processing

Title 5 U.S.C. § 552(a)(6)(E) provides for expedited processing of requests for information in cases in which the person requesting the records demonstrates a compelling need. By statute, for requests made by persons primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged federal government activity constitutes a "compelling need." 5 U.S.C. § 552(a)(6)(E)(v)(II). In addition, Department of Justice regulations state that FOIA requests are entitled to expedited processing when the information requested involves "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." 28 C.F.R. § 16.5(d)(1)(iv).

FDA regulations specifically provide for expedited processing, when "[w]ith respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." 21 C.F.R. § 20.44(a)(2). The FDA regulations further state:

> A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:
>
> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c).

Here, the requestors of this information are primarily engaged in disseminating information and, for reasons made clear below, there is urgency to inform the public concerning how state officials have acquired and are currently acquiring controlled substances to use in executions, and the role of federal officials in this process.[3] State officials are currently seeking to move forward with executions using controlled substances obtained from outside the United States and to acquire more of the lethal drugs. The value of the information to the public will be lost if not obtained and disseminated quickly, before additional executions occur using drugs of questionable origin and efficacy. FDA and other Federal government officials have been directly involved in the acquisition by state officials of controlled substances for purposes of execution. The acquisition of controlled substances for use in execution has been widely reported, caused widespread anxiety, and raised widespread concerns about potential misconduct by state and federal government officials.

1. Requestors.

The American Civil Liberties Union of Northern California (including the ACLU Foundation of Northern California), is an affiliate of the ACLU, a national organization that works to protect the civil liberties of all people, including the safeguarding of the basic constitutional rights to privacy, free expression, and due process of law. The ACLU-NC is responsible for serving the

[3] In 2006, a federal court ordered the Department of Defense to comply with a request for expedited processing request by the ACLU-NC and the *Guardian. ACLU-NC, et. al. v. Dept. of Defense*, 2006 WL 1469418, Case No. 06-01698 (N.D. Cal. May 25, 2006). *See also American Civil Liberties Union v. Dept. of Defense*, 339 F.Supp. 2d 501 (S.D.N.Y. 2004) (setting schedule for disclosure of documents to ACLU under expedited processing request).

population of northern California. The communications department of the ACLU-NC is the division of the ACLU-NC that is responsible for disseminating information to the public about issues of concern to the ACLU-NC and to the general public.

The *San Francisco Bay Guardian* is the largest circulation newsweekly in northern California, with an audited weekly distribution of 100,000. The paper is locally owned, independent, and has been published continuously since 1966.

2. Particular Value That Will Be Lost.

As documented in the news articles below, states including California and Arizona are actively and aggressively seeking to carry out executions of condemned inmates by lethal injection using controlled substances obtained from outside the United States. The origin, legality and efficacy of these controlled substances remain very much in question. The public has an urgent need to know where these lethal drugs came from, what they are, how well they work, and how they got into the country. There is a particular and unique value of this information to the public that will be lost if not obtained and disseminated quickly, before another state is allowed to carry out an execution using controlled substances obtained from outside the United States.

3. Widespread Media Interest and Concerns Regarding Federal Government Activities.

Since May 2010, there has been extensive news coverage around the country about how state officials are acquiring the controlled substances used in executions. More than 139 separate stories have been published, appearing in hundreds of media outlets in the United States and internationally. The issue has been covered by the largest media outlets, including the Associated Press, New York Times, Wall Street Journal, USA Today, Christian Science Monitor, CNN, MSNBC, and NPR. This widespread media attention demonstrates the public interest and concern over the potential for improper government activity in the acquisition of these controlled substances which are lethal and dangerous drugs.[4]

In May, 2010, media outlets began reporting that one of the controlled substances commonly used in executions in the United States, sodium thiopental, was unavailable due to production problem with the only FDA-approved, domestic supplier of the drug, Hospira. Soon after this was revealed, media outlets began reporting that the shortage of sodium thiopental was resulting in delays in executions in some states.

> *See* Andrew Welsh-Huggins, "Worldwide shortage of death penalty drug threatened upcoming Ohio execution," Associated Press, May 11, 2010 (Appendix A, Tab 1); Michael Kiefer, "Drug shortage may imperil executions in Arizona," Arizona Republic, May 17, 2010 (Appendix A, Tab 2); Jessie Hallady, "Anesthesia shortage may delay executions," USA Today, August 28, 2010 (Appendix A, Tab 3); Lucile Malandain, "Lethal drug supply dries up, postponing US executions," Agence France-Presse, September 4, 2010 (Appendix A, Tab 4); Julie Kent, "US States to Postpone Executions as Lethal Drug Runs Out," Cleveland Ledger, September 5, 2010 (Appendix A, Tab 5);

[4] The news articles mentioned in this letter are attached hereto as Appendix A.

Kathy Lohr, "States Delay Executions Owing To Drug Shortage," NPR All Things Considered, September 16, 2010 (Appendix A, Tab 6); Andrew Welsh-Huggins, "Some US executions held up by shortage of drug," Associated Press, September 28, 2010 (Appendix A, Tab 7); Mike Ward, "Drug shortage threatens executions, but not in Texas," Austin American Statesman, September 28, 2010 (Appendix A, Tab 8); Mike Tolson, "Drug shortage delays some executions, but not in Texas," Houston Chronicle, September 28, 2010 (Appendix A, Tab 9); Kevin Sack, "Shortage of Widely Used Anesthetics Is Delaying Executions in Some States," New York Times, September 29, 2010 (Appendix A, Tab 10); "Drugs shortage halts US executions," UK Associated Press, September 29, 2010 (Appendix A, Tab 11).

As the shortage began to impact executions, attorneys, community members and journalists began asking questions and expressing concern over how state corrections officials would obtain sodium thiopental, whether government officials would violate any state or federal law in their effort to obtain the drug, the efficacy of the drugs in their possession, and what other steps officials might take in order to proceed with executions.

See Michael Baker, "Federal judge issues stay of execution for Oklahoma death row inmate," Oklahoman, August 18, 2010 (Appendix A, Tab 12); Al Tompkins, "States Deal with Impact of Death Penalty Drug Shortage," Poynter, August 26, 2010 (Appendix A, Tab 13); Claudia Coffey, "Ky. governor holding off on some executions due to shortage of key drug," WHAS11.com, August 26, 2010 (Appendix A, Tab 14); Michael Baker, "Shortage of death penalty drug in Oklahoma delays executions," Oklahoman, September 13, 2010 (Appendix A, Tab 15); Lucile Malandain, "Drug shortage throws US executions into disarray," Agence France-Presse, October 25, 2010 (Appendix A, Tab 16); "Arkansas supplied drug used in recent Oklahoma execution," Associated Press, November 8, 2010 (Appendix A, Tab 17); Rina Palta, "Inside the evolving market for lethal injection drugs," KALW Informant, November 9, 2010 (Appendix A, Tab 18); Nathan Koppel, "New Execution Drug Approved," Wall Street Journal, November 19, 2010 (Appendix A, Tab 19); Koppel, "The Sun Shines In Texas on Lethal Injection," Wall Street Journal, November 19, 2010 (Appendix A, Tab 20); Kathy Lohr, "Okla. considers using vet drug to execute inmate," NPR Morning Edition, November 19, 2010 (Appendix A, Tab 21); Mike Ward, "Texas has lethal drugs on hand to execute 39 condemned criminals," Austin American Statesman, November 19, 2010 (Appendix A, Tab 22); Kevin Horrigan, "Capital punishment: How will Missouri "lethally inject" if it runs out of a lethal drug?" St. Louis Today, November 21, 2010 (Appendix A, Tab 23); Sam Stanton and Denny Walsh, "Drug shortage stirs death penalty debate in the U.S. and beyond," Sacramento Bee, December 5, 2010 (Appendix A, Tab 24); "Oklahoma executes man using new drug combination," Associated Press, December 16, 2010 (Appendix A, Tab 25).

An execution in California scheduled for September 30, 2010, was delayed in part because the state's supply of sodium thiopental expired on October 1, and the state was unable to lawfully acquire a new supply of the controlled substance. The issue generated enormous media coverage in the state and nationally.

See Jesse McKinley and Malia Wollan, "Governor Postpones Execution in California," New York Times, September 27, 2010 (Appendix A, Tab 26); Michael Winter, "Drug shortage prompts Calif. to suspend executions after Sept. 30," USA Today, September 27, 2010 (Appendix A, Tab 27); Howard Mintz, "Execution drama unfolds in California," San Jose Mercury News, September 27, 2010 (Appendix A, Tab 28); Jesse McKinley and Malia Wollan, "Judges Cancels California Execution," New York Times, September 28, 2010 (Appendix A, Tab 29); CNN Wire Staff, "Court ruling may stall California execution," CNN, September 28, 2010 (Appendix A, Tab 30); Paul Elias, "Court orders hearing for condemned Calif. Inmate," Associated Press, September 28, 2010 (Appendix A, Tab 31); Carol Williams, "California's first execution in five years delayed by legal issues," Los Angeles Times, September 28, 2010 (Appendix A, Tab 32); Sam Stanton, "Death penalty reprieve ordered," Sacramento Bee, September 28, 2010 (Appendix A, Tab 33); Bob Egelko, "Court sends execution case back to U.S. judge," San Francisco Chronicle, September 28, 2010 (Appendix A, Tab 34); Julia Cheever, "Appeals Court Orders Federal Judge To Reconsider Stay Of Execution Request For San Quentin Inmate," Bay City News, September 28, 2010 (Appendix A, Tab 35); Paul Elias, "Fed judge blocks Calif. execution set for Thursday," Associated Press, September 29, 2010 (Appendix A, Tab 36); Paul Elias, "Calif execution try collapses after court setbacks," Associated Press, September 29, 2010 (Appendix A, Tab 37); Howard Mintz, "With time running out, judge blocks execution," San Jose Mercury News, September 29, 2010 (Appendix A, Tab 38); Kevin Fagan, "Execution: Expiration date near for death drug," San Francisco Chronicle, September 29, 2010 (Appendix A, Tab 39); Denny Walsh, "Federal judge halts scheduled Thursday execution," Sacramento Bee, September 29, 2010 (Appendix A, Tab 40); Carol Williams, "Judge halts execution of rapist-murderer," Los Angeles Times, September 29, 2010 (Appendix A, Tab 41); Vauhini Vara and Nathan Koppel, "Spotlight on Injection Drug as Judge Stays Execution," Wall Street journal, September 30, 2010 (Appendix A, Tab 42); Jack Leonard and Victoria Kim, "California Supreme Court ends legal battle over execution," Los Angeles Times, September 30, 2010 (Appendix A, Tab 43); Denny Walsh and Sam Stanton, "State drops effort to execute rapist-murderer by today," Sacramento Bee, September 30, 2010 (Appendix A, Tab 44); Howard Mintz, "No Executions in '10," San Jose Mercury News, September 30, 2010 (Appendix A, Tab 45); Julia Cheever, "Supreme Court Blocks Execution Of San Quentin Man, Schwarzenegger Decries Decision," Bay City News, September 30, 2010 (Appendix A, Tab 46).

At the end of September, the state of Arizona suddenly acquired a new supply of sodium thiopental. The state eventually revealed that it had imported the sodium thiopental from the United Kingdom, but did not explain how it had imported the drug despite the fact that federal law prohibits importation of controlled substances from sources that are not approved by the FDA. The origin and legality of the Arizona drug became the focus of an intense legal battle with extensive local, national and international media coverage.

See "Arizona says it may get drug needed for execution," Associated Press, September 23, 2010 (Appendix A, Tab 47); Michael Kiefer, "Arizona Supreme Court puts execution on hold," Arizona Republic, September 24, 2010 (Appendix A, Tab 48); Michael Kiefer, "Arizona death row inmate's lawyers want drug info from state," Arizona

Republic, October 15, 2010 (Appendix A, Tab 49); James Clark, "Some Call it Murder: Breaking the Law in the Name of Capital Punishment," Change.org, October 15, 2010 (Appendix A, Tab 50); Paul Davenport, "Arizona execution caught in drug supply debate," October 19, 2010 (Appendix A, Tab 51); Michael Kiefer, "Judge asks Arizona for execution-drug source," Arizona Republic, October 21, 2010 (Appendix A, Tab 52); "Ariz. inmate files suit challenging execution drug," Associated Press, October 21, 2010 (Appendix A, Tab 53); John Schwartz, "Use of Drug Challenged in Death Penalty Case," New York Times, October 23, 2010 (Appendix A, Tab 54); Michael Kiefer, "Arizona told to reveal source of drug for execution," Arizona Republic, October 23, 2010 (Appendix A, Tab 55); John Schwartz, "Arizona: Drug Question Holds Up Execution," New York Times, October 25, 2010 (Appendix A, Tab 56); Paul Davenport, "Judge blocks Arizona execution, state appeals," Associated Press, October, 25, 2010 (Appendix A, Tab 57); "Inmate's lawyers ask judge to discuss drug info," Associated Press, October 25, 2010 (Appendix A, Tab 58); "State ordered to reveal info about drug for execution use," Associated Press, October 25, 2010 (Appendix A, Tab 59); "Arizona submits info on execution drugs to judge," Associated Press, October 25, 2010 (Appendix A, Tab 60); "Judge puts off Arizona execution, saying state not forthcoming," CNN, October 25, 2010 (Appendix A, Tab 61); Michael Kiefer, "Judge to question whether Arizona illegally obtained lethal-injection drug," Arizona Republic, October 25, 2010 (Appendix A, Tab 62); "Brewer Denies Delay In Landrigan Execution," KPHO-TV, October 25, 2010 (Appendix A, Tab 63); James Clark, "Sudden Secrecy Surrounds Death Penalty Drugs," Change.org, October 25, 2010 (Appendix A, Tab 64); Michael Kiefer, "Judge delays execution set for today," Arizona Republic, October 26, 2010 (Appendix A, Tab 65); "US execution blocked in row over lethal drug source," Agence France-Presse, October 26, 2010 (Appendix A, Tab 66); George Miller, "Inmate delays execution through drug-source protest," Fierce Pharma Manufacturing, October 26, 2010 (Appendix A, Tab 67); John Schwartz, "Murderer executed in Arizona," New York Times, October 27, 2010 (Appendix A, Tab 68); Nina Totenberg, "Supreme Court OKs Foreign Lethal Injection Drug," NPR, October 27, 2010 (Appendix A, Tab 69); "State Goes Overseas For Lethal Injection Drug," Associated Press, October 27, 2010 (Appendix A, Tab 70); "Arizona convicted killer's last words: 'Boomer Sooner,'" CNN, October 27, 2010 (Appendix A, Tab 71); Michael Kiefer, "Arizona executes inmate after federal judge lifts stay," Arizona Republic, October 27, 2010 (Appendix A, Tab 72); "Arizona executes man after Supreme Court green light," Agence France-Presse, October 27, 2010 (Appendix A, Tab 73); David Savage, "Justice Elena Kagan's first vote is against an execution," Los Angeles Times, October 27, 2010 (Appendix A, Tab 74); Victoria Ward, "Arizona execute man with drug supplied by British company," Telegraph, October 27, 2010 (Appendix A, Tab 75); Chris McGreal, "Arizona execution goes ahead after stay lifted," Guardian, October 27, 2010 (Appendix A, Tab 76); Rina Palta, "What the Arizona execution means for the death penalty nationwide," KALW Informant, October 27, 2010 (Appendix A, Tab 77); Tony Mauro, "High Court Split Paves Way for Arizona Execution," National Law Journal, October 28, 2010 (Appendix A, Tab 78); Joan Biskupic and Kevin Johnson, "Justices not convinced by arguments to delay execution," USA Today, October 28, 2010 (Appendix A, Tab 79); George Miller, "Report: Archimedes anesthetic used in Arizona execution," Fierce Pharma Manufacturing, October 28, 2010 (Appendix A, Tab 80).

Although Arizona was able to carry out one execution using the controlled substance imported from the United Kingdom, the action was criticized and continues to raise serious legal questions. The Arizona Supreme Court subsequently delayed an execution due to questions about the origin and efficacy of the drug.

> *See* Dahlia Lithwick, "Lethal Deflection," Slate.com, October 28, 2010 (Appendix A, Tab 81); New York Times Editorial, "No Justification," October 29, 2010 (Appendix A, Tab 82); James Clark, "Jeffrey Landrigan Executed by Arizona Amid Continued Secrecy," Change.org, October 30, 2010 (Appendix A, Tab 83); "Lawyer files complaint over British execution drug," Agence France-Presse, November 19, 2010 (Appendix A, Tab 84); Michael Kiefer, "Arizona Supreme Court puts off date for execution," Arizona Republic, December 1, 2010 (Appendix A, Tab 85).

On October 6, 2010, the California Department of Corrections and Rehabilitation disclosed that it too had recently obtained 12 grams of sodium thiopental, with an expiration date of 2014, despite the nationwide shortage. The CDCR did not disclose the source of the drug or explain how it came into possession of the scare substance. Because the last supply of sodium thiopental produced by Hospira has an expiration date of 2011, the sodium thiopental in the CDCR's possession could not have been manufactured domestically.

> *See* Carol Williams, "State has enough sodium thiopental to execute four," Los Angeles Times, November 8, 2010 (Appendix A, Tab 86); "Drug issue stalls executions in California," UPI, November 8, 2010 (Appendix A, Tab 87); Julie Small, "Corrections chief promises to divulge how California secured lethal injection drug," KPCC, November 19, 2010 (Appendix A, Tab 88); James Clark, "State refuses to give up lethal drug dealer," Change.org, November 22, 2010 (Appendix A, Tab 89).

The ACLU-NC filed a request under the California Public Records Act (PRA) to get records regarding the CDCR's acquisition of sodium thiopental. The *Guardian,* the Village Voice and the Associated Press also filed PRA requests seeking the records. Because the CDCR failed to respond to any of these requests, the ACLU-NC subsequently filed suit to enforce the PRA request, resulting in a court order that forced the CDCR to disclose the records.

> *See* Rina Palta, "ACLU: Where did California get its execution drugs?" KALW Informant, November 18, 2010 (Appendix A, Tab 90); Ryan Gabrielson, "ACLU sues state over lethal injection drug," California Watch, November 19, 2010 (Appendix A, Tab 91); Carol Williams, "State ordered to reveal source of its lethal-injection drug," Los Angeles Times, December 2, 2010 (Appendix A, Tab 92); Julie Small, "California prison officials ordered to disclose information on lethal injection drug," KPCC, December 2, 2010 (Appendix A, Tab 93); Rina Palta, "Judge: California must make execution drug records public," KALW Informant, December 2, 2010 (Appendix A, Tab 94).

The day before releasing the records to the ACLU-NC, the CDCR disclosed to selected journalists that it had ordered 521 grams of sodium thiopental manufactured by a company in the

United Kingdom and that the state paid more than $36,000 to acquire the drug. The CDCR told the journalists that the controlled substance had arrived in the United States but was currently in the procession of the FDA awaiting inspection.

> *See* Paul Elias, "Calif gets supply of drug used during executions," Associated Press, December 6, 2010 (Appendix A, Tab 95); Rina Palta, "Where California got its execution drugs," KALW Informant, December 6, 2010 (Appendix A, Tab 96); Paul Elias, "San Quentin gets supply of drug used during executions," Associated Press, December 7, 2010 (Appendix A, Tab 97); Sam Stanton, "Execution drug came from UK, CA officials say," Sacramento Bee, December 7, 2010 (Appendix A, Tab 98); Carol Williams, "California now has enough drugs to execute 175 death row inmates," Los Angeles Times, December 7, 2010 (Appendix A, Tab 99); "California buys execution drug from Britain," Agence France-Presse, December 7, 2010 (Appendix A, Tab 100); Rula Al-Nasrawi, "Secrets of the state's death-drug deal," San Francisco Bay Guardian, December 7, 2010 (Appendix A, Tab 101); Julie Small, "Prisons release details of lethal injection drug acquisition," KPCC-FM, December 8, 2010 (Appendix A, Tab 102); James Clark, "California reveals its drug dealer," Change.org, December 8, 2010 (Appendix A, Tab 103); "California Bought Scarce Lethal-Injection Drug From British Firm," Crime Report, December 8, 2010 (Appendix A, Tab 104); "CA Waiting For Lethal Injection Drug Approval," Corrections.com, December 8, 2010 (Appendix A, Tab 105).

The CDCR produced 980 pages of records regarding the acquisition of execution drugs to the ACLU-NC on December 8, 2010. The ACLU-NC posted the documents to its website the same day. Since posting, the page has been visited 2,213 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website. The records are available at:

> http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response_to_aclu_public_records_act_request.shtml.

The records disclosed by the CDCR raise serious questions about the conduct of state and federal government officials, and raise concern that state and federal laws were violated by the states' recent acquisition of sodium thiopental and by exchanges of controlled substances between different states. The information revealed in the records generated widespread media coverage in California, nationally and internationally.

> *See* Julie Small, "California's Corrections Department swapped lethal drugs with Arizona," KPCC, December 8, 2010 (Appendix A, Tab 106); George Miller, "Fierce Pharma Mfg - Imported death penalty drug to be tested by FDA," Fierce Pharma Manufacturing, December 8, 2010 (Appendix A, Tab 107); Paul Elias, "Docs show Calif.'s worldwide execution drug search," Associated Press, December 9, 2010 (Appendix A, Tab 108); Paul Elias, "Calif. scrambled for execution drug," Associated Press, December 9, 2010 (Appendix A, Tab 109); Rina Palta, "Timeline: California's scramble for execution drugs," KALW Informant, December 9, 2010 (Appendix A, Tab 110); Natasha Minsker, "I've got a secret mission for you," ACLU Blog of Rights,

December 9, 2010 (Appendix A, Tab 111); Jeff Neumann, "Arizona prison officials called 'life savers' for sharing lethal drug," Gawker.com, December 9, 2010 (Appendix A, Tab 112); Mike Ward, "California: Texas officials turned down request for execution drug," Statesman.com, December 9, 2010 (Appendix A, Tab 113); David Usborne, "Emails reveal gallows humour on death row," Independent, December 10, 2010 (Appendix A, Tab 114); Christopher Brauchli, "The executioner's drugs," Counter Punch, December 10, 2010 (Appendix A, Tab 115); Anthony Lydgate, Weekly Review, Harper's Magazine, December 14, 2010 (Appendix A, Tab 116); "Mysteries of the death-drug scramble," *San Francisco Bay Guardian*, December 14, 2010 (Appendix A, Tab 117); Ryan Gabrielson, "State withholds name of lethal drug supplier," California Watch, December 17, 2010 (Appendix A, Tab 118).

See also The Colbert Report, Tiny Triumphs—Lethal Drug Shortage, available at: http://www.colbertnation.com/the-colbert-report-videos/368731/december-15-2010/tiny-triumphs---lethal-drug-shortage?xrs=share_copy

In addition, the fact that state officials have been importing sodium thiopental from the United Kingdom has generated significant public outcry, legal challenges, and media attention, both in the United Kingdom, and in the United States. Following disclosure that states in the U.S. were acquiring execution drugs from sources in the UK, the government of the United Kingdom imposed new restrictions preventing the export of sodium thiopental for purposes of execution.

See Clive Stafford Smith, "The British company making a business out of killing," Guardian, October 26, 2010 (Appendix A, Tab 119); Owen Bowcott and Chris McGreal, "British firm denies exporting drug for Arizona execution," Guardian, October 27, 2010 (Appendix A, Tab 120); Robert Verkaik, "British company link to drug used in execution," Independent, October 27, 2010 (Appendix A, Tab 121); Michael Seamark, "British company denies exporting drug used in US execution after Arizona's supplies run dry," Daily Mail, October 28, 2010 (Appendix A, Tab 122); Ian Dunt, "Cable under fire for allowing execution drug sale," Politics.com, November 2, 2010 (Appendix A, Tab 123); David Cronin, "Not Executing, Just Enabling, IPS News, November 4, 2010 (Appendix A, Tab 124); Paddy, McGuffin, "Cable in court over death drug export," UK Morning Star, November 17, 2010 (Appendix A, Tab 125); "Cable attacked on 'execution drug.'" UK Press Associated, November 17, 2010 (Appendix A, Tab 126); John Aston, "Bid to ban export of 'execution' drug," Independent, November 17, 2010 (Appendix A, Tab 127); Benjamin Timmins, "British imposes controls on lethal injection drug," Associated Press, November 29, 2010 (Appendix A, Tab 128); Clive Stafford Smith, "A welcome U-turn from Vince Cable on execution drug," Guardian, November 29, 2010 (Appendix A, Tab 129); Michael Kiefer, "Controls imposed on lethal injection drug Arizona uses," Arizona Republic, November 29, 2010 (Appendix A, Tab 130); Dominic Casciani, "US lethal injection drug faces UK export restrictions," BBC, November 29, 2010 (Appendix A, Tab 131); Peter Walker, "Vince Cable restricts export of drug used in US executions," Guardian, November 29, 2010 (Appendix A, Tab 132); Daily Mail Reporter, "Human rights victory as Vince Cable imposes restrictions," November 29, 2010 (Appendix A, Tab 133); Tim Edwards, "Cable restricts export of lethal injection drug to US," First Post, November 29, 2010 (Appendix A, Tab 134);

Nathan Koppel and Jeanne Whalen, "U.K. Limits Execution Drug's Export," Wall Street Journal, November 30, 2010 (Appendix A, Tab 135); "U.K. to limit export of execution drug widely used in U.S.," MSNBC, November 30, 2010 (Appendix A, Tab 136); James Clark, "America's death penalty looses and ally," Change.org, November 30, 2010 (Appendix A, Tab 137); Mark Townsend, "US execution drugs supplied secretly by British companies," Guardian, December 19, 2010 (Appendix A, Tab 138); Paddy McGuffin, "Lethal drugs secretly shipped to California," UK Morning Star, December 19, 2010 (Appendix A, Tab 139).

As the forgoing demonstrates, questions about how state officials are acquiring controlled substances to use in executions and the role of federal officials in that process have generated exceptional, widespread media coverage in the United States and across the globe. The issue raises substantial questions about the integrity of government, at the state and federal level. The public has an urgent need for additional information as state officials continue to pursue new acquisitions of controlled substances for executions and seek to use substances in their possession of questionable origin and efficacy. The particular value of this information to the public will be lost if not obtained and disseminated quickly. For these reasons, the FDA should grant expedited processing of this FOIA request.

III. "Public Interest" Fee Waiver Request

We request a waiver of document search, review, and duplication fees on the grounds that disclosure of the requested records is in the public interest because disclosure is "likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." *See* 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. 20.46(a); see also 28 C.F.R. § 16.11(k)(1).

The FDA regulations further specify that the FDA will consider the following factors when determining if disclosure is in the public interest:

> (1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;
>
> (2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;
>
> (3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

(4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

All of these factors are met here. First, the records sought pertain to the role of the FDA and other government officials in facilitating the acquisition by state officials of controlled substances for the purpose of execution. Second, disclosure of the records would reveal significant information that is currently unknown, specifically the details of how state officials acquired non-FDA approved controlled substances from outside the United States. Third, disclosure will assist the public generally in understanding a critical aspect of the capital punishment process in the United States and the requesters are in a position to disseminate the information broadly, as detailed below. Fourth, contributing to the public's understanding of the capital punishment process is a substantial and weighty public interest.

The requestors plan to disseminate widely to the public records disclosed as a result of this FOIA request. The ACLU-NC's communications department is a division of a nonprofit 501(c)(3) organization, and both the ACLU-NC's communications department and the *Guardian* are "representative[s] of the news media." They are well situated to disseminate information gained through this request to the public, to affected communities and to political and legal organizations. The requestors routinely obtain information about government activity (including through FOIA), analyze that information, and widely publish and disseminate that information to the press and to the public in a variety of ways including the following:

The ACLU-NC's communications department disseminates information through the website, http://www.aclunc.org, which had 477,995 page views in 2010. This website addresses civil liberties issues in depth and provides features on civil liberties issues on which the ACLU-NC is focused. As noted, the ACLU-NC posted the documents obtained from the CDCR regarding the acquisition of execution drugs on the day it received the records, December 8, 2010. Since posting, the page has been visited 2,835 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website.

The ACLU-NC's communications department also publishes reporters, news briefings, right-to-know documents, and other materials that are disseminated to the public. Its material is widely available to everyone, including tax-exempt organizations, not-for-profit groups, law students and faculty, for no cost. ACLU-NC staff persons are frequent spokespersons in television and print media and make frequent public presentations at meetings and events. Finally, the ACLU-NC's communications department disseminates information through a newsletter, which is distributed to subscribers by mail. Due to these extensive publication activities, the ACLU-NC is a "representative of the news media" under the FOIA and agency regulations.

As noted, the *Guardian* is the largest circulation newsweekly in northern California, with audited weekly distribution of 100,000 copies. The paper covers breaking news, does detailed investigative reporting, publishes editorials and covers arts, entertainment, and lifestyle issues. The *Guardian* has received more than 100 state, local and national awards for journalistic

excellence. The *Guardian* is a member of the California Newspaper Publishers Association and the Association of Alternative Newsweeklies.

Finally, disclosure of the requested records is not in the requestors' commercial interest. See 21 C.F.R. § 20.46(c). The records requested are not sought for commercial use and the ACLU-NC plans to disseminate the information disclosed as a result of this FOIA request to the public at no cost. Thus, a fee waiver would fulfill Congress's legislative intent in amending FOIA. *See Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be 'liberally construed in favor of waivers for noncommercial requesters.'") (citation omitted).

IV. News Media Status Fee Limitation Request

We also request a waiver of document search and reproduction fees on the grounds that the requestors qualify as "representatives of the news media" and the records are not sought for commercial use. 21 C.F.R. § 20.45(a)(2). The *Guardian* is a newsweekly. The ACLU-NC also meets the statutory and regulatory definitions of a "representative of the news media" because they are "entit[ies] that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." 5 U.S.C. § 552(a)(4)(A)(ii); *see also Nat'l Sec. Archive v. Dep't of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989) (finding that an organization that "gathers information from a variety of sources," exercises editorial discretion in selecting and organizing documents, "devises indices and finding aids," and "distributes the resulting work to the public" is a "representative of the news media" for purposes of the FOIA); *cf. ACLU v. Dep't of Justice*, 321 F. Supp. 2d at 30 n.5 (finding non-profit public interest group to be "primarily engaged in disseminating information").[5]

Notably, courts have found other organizations whose missions, functions, publishing, and public education activities are similar in kind to the ACLU's to be "representatives of the news media." *See, e.g., Elec. Privacy Info. Ctr. v. Dep't of Defense*, 241 F. Supp. 2d 5, 10-15 (D.D.C. 2003) (finding non-profit public interest group that disseminated an electronic newsletter and published books was a "representative of the media" for purposes of FOIA); *Nat'l Security Archive*, 880 F.2d at 1387; *Judicial Watch, Inc. v. Dep't of Justice*, 133 F. Supp. 2d 52, 53-54 (D.D.C. 2000) (finding Judicial Watch, self-described as a "public interest law firm," a news media requester).[6]

[5] Fees associated with responding to FOIA requests are regularly waived for the ACLU, and a number of agencies have determined that the ACLU is a "representative of the news media" for the purposes of FOIA, including the Departments of Justice, State, and Commerce. In December 2008, the Department of Justice found that the ACLU was a "representative of the news media" for the purposes of FOIA in the context of a request for documents relating to the detention, interrogation, treatment, or prosecution of suspected terrorists.

[6] Courts have founds these organizations to be "representatives of the news media" even though they engage in litigation and lobbying activities beyond their dissemination of information/public education activities. *See, e.g., Elec. Privacy Info. Ctr.*, 241 F. Supp. 2d 5; *Nat'l Sec. Archive*, 880 F.2d at 1387; *see also Judicial Watch, Inc.*, 133 F. Supp. 2d at 53-54; *see also Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 260 (D.D.C. 2005) (finding Leadership Conference to be primarily engaged in disseminating information even though it engages in substantial amounts of legislative advocacy beyond its publication and public education functions).

* * *

If this request is denied in whole or in part, we ask that you justify all withholdings by reference to specific exemptions to the FOIA. We expect the release of all segregable portions of otherwise exempt material. If the fee waivers are denied, the requesters are prepared to pay fees up to $100, and request to be informed of further fees that may be charged, but reserve the right to appeal a denial of fee waivers.

Thank you for your prompt attention to this matter. Please furnish all applicable records to Natasha Minsker, American Civil Liberties Union of Northern California, 39 Drumm Street, San Francisco, California 94111, telephone (415) 621-2493, email nminsker@aclunc.org.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

Certification

Pursuant to 21 C.F.R. § 20.44(d), I, Natasha Minsker, certify that the information in this request is true and correct to the best of my knowledge and belief.

January 4, 2011

Signed in San Francisco, California

Natasha Minsker

EXHIBIT B

ACLU
AMERICAN CIVIL LIBERTIES UNION of
GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

February 15, 2011

U.S. Food and Drug Administration
Division of Freedom of Information HFI-35
5600 Fishers Lane Room 6-30
Rockville, MD 20857

Re: FOIA Appeal, Reference # 2011-319

Dear FOIA Officer:

Requestors American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) write to request reconsideration of the Food and Drug Administration's (FDA) decision to withhold materials or information in the records released in response to FOIA Request # 2011-319 (the "Request").

The Request seeks records pertaining to the acquisition of controlled substances by state officials for the purpose of carrying out executions of condemned prisoners by lethal injection. *See* Exh. A (FOIA Request dated January 4, 2011). Requestors received two responses from Legal Administrative Specialist Timothy J. Trepagnier, dated January 19, 2011 and February 8, 2011. Exh. B (Response to FOIA Request from Timothy J. Trepagnier dated January 19, 2011), Exh. C (Response to FOIA Request from Timothy J. Trepagnier dated February 8, 2011). Mr. Trepagnier's January 19 letter was accompanied by 63 pages of redacted documents (the "January 19 release") and his February 8 letter was accompanied by 49 pages of redacted documents (the "February 8 release"), some of which overlapped with the January 19 release. Both letters responding to the Request stated that certain material was redacted from the records produced by the FDA because the FDA preliminarily determined that such information was not required to be publicly disclosed and disclosure was not appropriate. *See* Exhs. B, C.

We respectfully request reconsideration of this preliminary determination and the release of unredacted information responsive to the Request. Requestors also seek apparently withheld documents, as well as clarification as to if and/or when the FDA will search files beyond those contained in its New Orleans District Office.

Redactions Pursuant to 5 U.S.C. § 552(b)

ACLU-NC and the *Guardian* requested the release of twelve distinct categories of information pertaining to the importation, transfer, or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution. In response, the New Orleans District Office released

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112 pages of heavily redacted material from the New Orleans District of the FDA, in two separate sets.[1] The FDA justifies the redactions by reference to four statutory exemptions:

- Exemption 4, 5 U.S.C. § 552(b)(4), which exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"

- Exemption 5, 5 U.S.C. § 552(b)(5), which exempts "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency,"

- Exemption 7(C), 5 U.S.C. § 552(b)(7)(C), which exempts "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information ... could reasonably be expected to constitute an unwarranted invasion of personal privacy," and

- Exemption 7(E), 5 U.S.C. § 552(b)(7)(E), which exempts law enforcement records or information, but only to the extent that production "would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law."

The FDA's inconsistent application of these exemptions, both within the releases as well as between the January 19 and February 8 releases, demonstrates that the FDA has incorrectly applied these exemptions and, as a result, is unlawfully withholding information the public has a right to receive. For example:

- The January 19 release includes an e-mail from Ruth Dixon to Domenic Veneziano, in which Ms. Dixon mentions that certain officials are "receiving significant pressure from the Governor's office." This e-mail appears in the February 8 release as well, but the part that mentions pressure from the Governor is redacted. *See* Exh. D (Comparison of Ruth Dixon e-mail dated December 9, 2010).

- In the January 19 release, all information that would identify the states that imported the drugs has been redacted. Those documents provided a second time in the February 8 release disclose this information. *See* Exh. E (Comparison of Susan Halpenny email dated December 20, 2010). Yet, because not all of the documents disclosed on January 19 were included in the February 8 release, much of the information about which states ordered the drugs still has not been released to the public.

- In a fax from the Arkansas Department of Correction, the redaction of quantity and price is marked (b)(4), which is an exemption for trade secrets or privileged financial information. *See* Exh. F (Fax from Arkansas Department of Correction dated September 10, 2010). But in a fax from the Georgia Department of Corrections, an essentially

[1] To date, the FDA has apparently not searched for responsive records beyond those in the New Orleans District's files, and has denied Requestors' request for expedited processing of their FOIA request. By separate letter dated February 1, 2011, Requestors have sought reconsideration of the denial of expedited processing.

identical redaction of quantity and price are marked (b)(7)(E), which exempts certain records that disclose techniques for law enforcement investigations or prosecutions. *See* Exh. G (Fax from Georgia Department of Corrections dated August 4, 2010).

Not only are these exemptions inapplicable, as discussed below, but the inconsistent redactions and inconsistent justifications for redaction show that the FDA is not consistently or accurately applying the exemptions to disclosure under FOIA, and that the agency does not have legal cause to withhold much of the information currently redacted from the documents.

Similarly, many of the redactions are so imprecise that they raise questions about whether the FDA is withholding critical information simply in error. Specifically, some blacklines result in redactions of surrounding text that plainly should not have been redacted. For example, an e-mail from David Thomas to Anthony Taube on September 27, 2010 appears several times, but depending on the font size of the printout, different portions of the text are blocked out. In one instance, the words immediately above and below a port of entry are deleted, but in other instances, smaller font and more precise blacklines reveal that the words "London" and "made" were improperly blocked out. *See* Exh. H (Comparison of David Thomas e-mail dated September 27, 2010). Several other instances of imprecise blacklining are scattered throughout the February 8 release, and it is likely that portions of records have been redacted unintentionally. *See, e.g.*, Exh. I (E-mail from David Thomas to Greta Budweg et al. dated September 27, 2010). Requestors seek full release of these improperly redacted materials.

Overall, the agency's redactions are excessive and unjustified. The quantity of drugs in each shipment has been redacted from all documents—FDA Notices of Action, Customs Entry forms, supplier invoices, and all other correspondence. Entire manifest reports and airbill entry forms have been blocked out, making it impossible to tell which agency, company, or state generated or received the document. *See, e.g.*, Exh. J (Manifest report dated June 28, 2010). Even if some of the redactions were proper under the referenced exemptions (which Requestors dispute), they are so numerous that they are far beyond any reasonable application of the exemptions. Furthermore, numerous redactions in the February 8 release are marked "NEC" which, as far as Requestors are aware, is not a category of permitted exemptions or any part of the Freedom of Information Act. To the extent the FDA has withheld information marked "NEC," we request that such information be disclosed or that the FDA provide an explanation for the withholding by reference to a statutory exemption under 5 U.S.C. § 552.

The redactions that do refer to statutory exemptions are also excessive. First, the liberal use of Exemption 5 is unwarranted. To qualify for protection under Exemption 5, a document must satisfy two conditions: "its source must be a Government agency, and it must fall within the ambit of a privilege against discovery under judicial standards that would govern litigation against the agency that holds it." *Department of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001). Requestors do not know the content or nature of all the (b)(5) redactions, but based on the examples we do have, it is unlikely that any of the redacted information qualifies under Exemption 5. Following are a sampling of improper applications of the exemption:

- In an e-mail from John Solomon of the South Carolina Department of Corrections, Mr. Solomon inquires whether a jurisdictional issue between the FDA and the DEA has been decided. He observes that if the question is not resolved soon, he "may be exchanging Christmas cards" with the FDA (January 19 release). This e-mail is also in the February 8 release, but both the reference to the jurisdictional problem and the remark about Christmas cards is redacted based on Exemption 5. *See* Exh. K (Comparison of John Solomon e-mail dated December 1, 2010). This redaction is improper: the question about

inter-agency jurisdiction does not reveal any privileged administrative deliberations, nor is the comment about exchanging holiday cards privileged.

- As noted above, the January 19 release includes an e-mail from Ruth Dixon to Domenic Veneziano, in which Ms. Dixon mentions that certain officials are "receiving significant pressure from the Governor's office." This comment has been redacted in the February 8 release, with Exemption 5 cited as the justification. *See* Exh. L (Comparison of Ruth Dixon e-mail dated December 9, 2010). This redaction is particularly disturbing because not only is there no privileged information in this sentence, it could also be construed as an attempt by the FDA to hide potential government misconduct, which goes against the primary purpose of the Freedom of Information Act.

- In another e-mail from Christopher Boulmay to John McAuliffe, part of a sentence is redacted under Exemption 7(E) in the January 19 release, but in the February 8 release, the entire sentence is redacted under Exemption 5. *See* Exh. M (Comparison of Christopher Boulmay e-mail dated November 30, 2010). Requestors dispute the applicability of either exemption, and the conflicting references to different exemptions suggests the FDA does not have a good reason for withholding the information.

These are just a few examples of the unjustified use of Exemption 5. For the reasons explained above, Requestors seek full disclosure of all materials withheld under the exemption.

Second, many of the redactions of price and quantity are marked as exempt under Exemption 4, but this exemption is inapplicable. The amount of money a state spends on lethal injection drugs is not privileged or confidential commercial or financial information or a trade secret. *See, e.g., Racal-Milgo Government Systems, Inc. v. Small Business Administration*, 559 F. Supp. 4 (D.D.C. 1981) (ordering disclosure of unit prices charged to the government for computer equipment and finding Exemption 4 inapplicable). The price a state pays for sodium thiopental, for example, is neither "a secret, commercially valuable plan, formula, process, or device … that can be said to be the end product of either innovation or substantial effort," *Public Citizen Health Research Group v. Food and Drug Administration*, 704 F.2d 1280, 1288 (D.C. Cir. 1983), nor is disclosure of such information likely to "impair the Government's ability to obtain necessary information in the future" or "cause substantial harm to the competitive position of the person from whom the information was obtained," *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). Moreover, the redacted prices are at least two to seven months old, as the most recent shipment has a recorded entry date of November 19, 2010. *See* Exh. N (Customs Entry form dated November 24, 2010). Historical prices are even less sensitive than current prices, and are very unlikely to impair the Government's ability to obtain information or goods in the future or cause competitive harm. Indeed, the California Department of Corrections and Rehabilitation (CDCR) has already disclosed records revealing that it paid $36,000 for one of the shipments covered by these FDA records.

Nor is the quantity of drugs purchased or imported exempt under Exemption 4: the public is entitled to be informed about how much drugs the government is buying to carry out executions and how much those drugs cost. This information is important because it allows citizens to decide whether the government is spending taxpayer money wisely. *See Racal-Milgo*, 559 F. Supp. at 6 ("Adequate information enables the public to evaluate the wisdom and efficiency of federal programs and expenditures."). The public has a right to know how and why a government agency decided to spend public funds as it did. *Martin Marietta Corp. v. Dalton*, 974 F. Supp. 37, 41 (D.D.C. 1997). *See also U.S. Department of Justice v. Reporters Committee for Freedom of Press*, 489 U.S. 749, 773 (1989) (basic purpose of the Freedom of Information Act "focuses on the citizens' right to be informed about what their

government is up to"). Again, the CDCR has already disclosed records showing that it purchased 521 grams of sodium thiopental from a source in the United Kingdom, in one of the shipments covered by these records.

In other price and quantity redactions, the FDA (inconsistently) makes reference to Exemption 7(E). Publication of the price and quantity of a lethal injection drug would not reveal any "techniques and procedures for law enforcement investigations or prosecutions," let alone create a reasonable expectation of risk of "circumvention of the law." As explained multiple times in the records, states are seeking to import the drugs to carry out death sentences—at this point, any investigation or prosecution should have long been concluded. Nor does disclosure provide any information that would help a person circumvent the law. Price and quantity numbers do not reveal any information about how an execution is carried out –the manner of execution and drugs used by each state is already public information. Thus, no techniques or procedures are compromised by disclosing information about price and quantity of drugs imported from abroad.

The FDA's reliance on Exemption 7(C) is also overbroad. In the January 19 release, Exemption 7(C) is used to prevent identification of state officials and even state names. Although the February 8 release discloses much of this information, Requestors do not know whether all of the information about the states that purchased or imported controlled substances has been identified because not all of the records contained in the January 19 release were included in the February 8 release. We request that all such information be released, as Exemption 7(C) does not apply here as the FDA belatedly realized.

Exemption 7(C) does not apply to this information because it is not an unwarranted invasion of *personal* privacy to reveal which *states* are purchasing, importing, or receiving controlled substances for the purpose of execution. Nor should the names of state officers be withheld, as "a government employee's privacy interests may be diminished to the extent it might disclose official misconduct." *Lissner v. U.S. Customs Service*, 241 F.3d 1220, 1223 (9th Cir. 2001). However, potential government misconduct is not required for disclosure of individual names: "Exemption 7(C) does not apply to information relating to business judgments and relationships when the information does not implicate any business actor in a crime.... An agency may not exempt from disclosure all of the materials in an investigatory record solely on the grounds that the record includes some information which identifies a private citizen or provides that person's name and address." *Center to Prevent Handgun Violence v. U.S. Department of Treasury*, 981 F. Supp. 20, 23-24 (D.D.C. 1997) (ordering release of names and locations of federal firearms licensees).

The FDA's own inconsistent application of 7(C) is telling. In the February 8 release, a letter from the General Counsel of California to the FDA mentions a state official (John McAuliffe), whose name is redacted based on Exemption 7(C). The same letter is also included in the January 19 release, but there, Mr. McAuliffe's name is not redacted. Elsewhere in the February 8 release, Mr. McAuliffe's name is left unredacted. This uneven disclosure is just one example of unnecessary redaction. We seek full release of any other information that has been unjustifiably withheld.

Even if the names of some individual state officers may be legitimately withheld in some documents, it is not reasonable to characterize disclosure of the identity of the *state* as an unwarranted invasion of personal privacy. To the extent the responsive records reveal the names of states, cities, government addresses, or government e-mail domain names, or refer to government officials' titles, Requestors dispute the FDA's decision to redact such information. This information falls outside the exemptions of Exemption 7(C) and therefore must be disclosed. At the very minimum, the FDA should

disclose the names of the states making each purchase, the area code for all phone numbers contained in the records, and the domain names for all email addresses.

Further, although Requestors cannot know all the types of information that have been redacted or withheld from the released records, we believe a large portion, if not all, of the redacted information is required to be publicly disclosed. The referenced exemptions under § 552(b) are inapplicable to much of the information that has been withheld. Requestors therefore seek reconsideration of the decision to redact any information, including as to the identities of the state or local governments that imported, transferred, or purchased the controlled substances, the quantities acquired, and the amounts paid, as well as any other information responsive to the Request.

Unreleased Records

The released documents appear to cover five shipments of controlled substances. The records for four of the shipments, released August 13, 2010 (Entry Number 112-7818637-8), September 28, 2010 (Entry Number 112-8992979-0), and January 6, 2010 (Entry Numbers 112-9673446-4 and 112-9938358-2), include "Notice of FDA Action" forms. However, records for Entry Number 112-9247186-3, which arrived on October 6, 2010, include a form from the U.S. Customs Service but no Notice of FDA Action. Was the Notice of FDA Action overlooked in the records search or was it intentionally withheld? Requestors seek production of this Notice. If the Notice was intentionally withheld, Requestors are entitled to know the reason(s) for the withholding.

Furthermore, the product description for the Entry Number 112-8992979-0 released on September 28, 2010 lists only Thiopental Sodium, but the e-mail correspondence related to this entry refers to "3 components of a lethal injection, 1) Thiopental, 2) Pancuronium, 3) Potassium Chloride." Were there additional entry forms or records for the pancuronium or potassium chloride? If so, Requestors seek production of these documents or the reason(s) for the withholding.

The same e-mail correspondence also makes reference to "UPS-9066861-5," appears to be another shipment. *See* Exh. O (E-mail from Greta Budweg dated September 27, 2010). Are there unreleased records related to this shipment, or any other shipments? If so, Requestors seek production of these documents or the reason(s) for the withholding.

Responses from Other Districts

All of the released records originated from the New Orleans District, and the letters accompanying the release described the documents as the result of a "search of the New Orleans District files," not of all the FDA files pertaining to the Request. *See* Exhs. B, C. Although the letters from Mr. Trepagnier states that Requestors "may hear from other FDA offices," we have received no indication whether other FDA district files will be searched or whether we will receive additional records from other districts, nor was there any explanation why other districts might not be searched. Without this information, we cannot know whether we need to object to additionally withheld materials. For this reason, we request that the FDA indicate which, if any, other district files will be searched and released.

* * *

For the foregoing reasons, we respectfully request that you reconsider the preliminary determination that the requested information is not required to be publicly disclosed and that the FDA confirm when offices other than the New Orleans District Office will be searched for responsive records. We look forward to your prompt response.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Also on behalf of Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

April 29, 2011

U.S. Food and Drug Administration
Division of Freedom of Information, HFI-35
OPILS/OSS/DFOI
1243 Parklawn Drive, Room 1050
Rockville, MD 20857

Re: FOIA Appeal, Reference # F11-319

Dear FOIA Officer:

Requestors American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) write to request reconsideration of the Food and Drug Administration's (FDA) decision to withhold materials or information in the records released in response to FOIA Request # 2011-319 (the "Request").

The Request seeks records pertaining to the acquisition of controlled substances by state officials for the purpose of carrying out executions of condemned prisoners by lethal injection. *See* Exh. A (FOIA Request dated January 4, 2011). Requestors received a response regarding records at the Los Angeles District Office of the FDA from Analyst John Bryce, dated March 31, 2011. *See* Exh. B (Response to FOIA Request from John Bryce dated March 31, 2011). Mr. Bryce's letter was accompanied by 35 pages of documents, many heavily redacted. The letter stated that certain material was redacted from the records produced by the FDA because the FDA preliminarily determined that such information was not required to be publicly disclosed and disclosure was not appropriate. *See* Exh. B.

We respectfully request reconsideration of this preliminary determination and the release of unredacted information responsive to the Request. We specifically request reconsideration of the redactions contained in the 18 pages attached to this letter as Exhibit C. Requestors also seek apparently withheld documents. We continue to seek clarification from the FDA on the timeline for searching other district offices and when we can anticipate full disclosure of all public records in this matter.

Redactions Pursuant to 5 U.S.C. § 552(b)

ACLU-NC and the *Guardian* requested the release of twelve distinct categories of information pertaining to the importation, transfer, or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution. In response, the Los Angeles District Office released 35 pages of heavily redacted material from the Los Angeles District of the FDA. The FDA justifies the redactions by reference to four statutory exemptions:

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- Exemption 4, 5 U.S.C. § 552(b)(4), which exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"

- Exemption 5, 5 U.S.C. § 552(b)(5), which exempts "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency,"

- Exemption 6, 5 U.S.C. § 552(b)(6), which exempts "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," and

- Exemption 7(E), 5 U.S.C. § 552(b)(7)(E), which exempts law enforcement records or information, but only to the extent that production "would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law."

The FDA's inconsistent application of these exemptions within this release demonstrates that the FDA has incorrectly applied these exemptions and, as a result, is unlawfully withholding information the public has a right to receive. For example, in the Entry/Immediate Delivery form for the shipment that arrived October 26, 2010 (Entry Number 574-0251126-5), the Importer of Record Name (field number 11) has been redacted without reason, although ostensibly based on Exemption 4 (as the rest of the page is). However, in the Entry/Immediate Delivery form for the shipment that arrived September 28, 2010 (Entry Number 574-0250322-1), the Importer of Record Name has been fully disclosed as the Arizona Department of Corrections ("DOC"). Not only are these exemptions inapplicable, as discussed below, but these inconsistent redactions show that the FDA is not consistently or accurately applying the exemptions to disclosure under FOIA, and that the agency does not have legal cause to withhold much of the information currently redacted from the documents.

Overall, the agency's redactions are excessive and unjustified. The quantity of drugs in each shipment has been redacted from all documents – FDA Notices of Action, Customs Entry forms, supplier invoices, and all other correspondence. The single Entry and Manifest Form released has been blocked out, making it impossible to tell which agency, company, or state generated or received the document. *See* Exh. D (Manifest report dated September 29, 2010). Even if some of the redactions were proper under the referenced exemptions (which Requestors dispute), they are so numerous that they are far beyond any reasonable application of the exemptions.

The redactions that do refer to statutory exemptions are also excessive. Many of the redactions of price and quantity are marked as exempt under Exemption 4, but this exemption is inapplicable. The amount of money a state spends on lethal injection drugs is not privileged or confidential commercial or financial information or a trade secret. *See, e.g.*, *Racal-Milgo Government Systems, Inc. v. Small Business Administration*, 559 F. Supp. 4 (D.D.C. 1981) (ordering disclosure of unit prices charged to the government for computer equipment and finding Exemption 4 inapplicable). The price a state pays for sodium thiopental, for example, is neither "a secret, commercially valuable plan, formula, process, or device … that can be said to be the end product of either innovation or substantial effort," *Public Citizen Health Research Group v. Food and Drug Administration*, 704 F.2d 1280, 1288 (D.C. Cir. 1983), nor is disclosure of such information likely to "impair the Government's ability to obtain necessary information in the future" or "cause substantial harm to the competitive position of the person from whom the

information was obtained," *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). Moreover, the redacted prices are at least six months old, as the most recent shipment has a recorded arrival date of October 26, 2010. *See* Exh. E (Customs Entry form dated October 26, 2010). Historical prices are even less sensitive than current prices, and are very unlikely to impair the Government's ability to obtain information or goods in the future or cause competitive harm. In most cases, the states have already publicly disclosed how much they paid for the execution drugs.

Nor is the quantity of drugs purchased or imported exempt under Exemption 4: the public is entitled to be informed about how much drugs the government is buying to carry out executions and how much those drugs cost. This information is important because it allows citizens to decide whether the government is spending taxpayer money wisely. *See Racal-Milgo*, 559 F. Supp. at 6 ("Adequate information enables the public to evaluate the wisdom and efficiency of federal programs and expenditures."). The public has a right to know how and why a government agency decided to spend public funds as it did. *Martin Marietta Corp. v. Dalton*, 974 F. Supp. 37, 41 (D.D.C. 1997). *See also U.S. Department of Justice v. Reporters Committee for Freedom of Press*, 489 U.S. 749, 773 (1989) (basic purpose of the Freedom of Information Act "focuses on the citizens' right to be informed about what their government is up to"). For example, the California Department of Corrections paid 35 times the market price for the execution drugs it imported from Dream Pharma.

The FDA also used Exemption 6 to redact the name of a case before the Arizona Supreme Court. Exh. F (email chain). It is difficult to see how a public case name is a "personnel" or "medical" file, or even anything "similar" to either of those two types of files. Furthermore, releasing the name of a case would hardly constitute "an unwarranted invasion of personal privacy." The FDA has therefore improperly applied Exemption 6 in this release.

The FDA has further used Exemption 7(E) to redact the DEA registration number for the Arizona Department of Corrections ("DOC"). *See* Exh. G (Email chain). This registration number would not reveal any "techniques and procedures for law enforcement investigations or prosecutions," let alone create a reasonable expectation of risk of "circumvention of the law." As explained multiple times in the records, states are seeking to import the drugs to carry out death sentences—at this point, any investigation or prosecution should have long been concluded. Disclosure also would not provide any information that would help a person circumvent the law. Thus, no techniques or procedures are compromised by disclosing the DEA registration number for the Arizona DOC.

Lastly, while Requestors cannot determine the content that has been redacted based on Exemption 5, because of the incorrect usage of the other exemptions, we ask for reconsideration of this redaction as well.

Unreleased Records

The released documents appear to cover two shipments of controlled substances. The records for one of the shipments, released September 29, 2010 (Entry Number 574-0250322-1), includes a Transportation Entry and Manifest of Goods Subject to CBP Inspection and Permit Form. However, the records for the other shipment, released January 6, 2011 (Entry Number 574-0251126-5) does not include this Entry and Manifest form. Was this form overlooked in the records search or was it intentionally withheld? Requestors seek production of this Entry and Manifest Form. If the Entry and Manifest Form was intentionally withheld, Requestors are entitled to know the reason(s) for the withholding.

As of today's date, we have received responsive records from the New Orleans and Los Angeles District Offices only. We received a small number of records from the main FDA office in Maryland, but all pertain only to the lawsuit filed by death row inmates against the FDA. The FDA has failed to produce large quantities of responsive records, such as internal communications about policies regarding the importation of controlled substances for executions. We again request full compliance and disclosure of all the records requested in our January 4th FOIA request.

* * *

For the foregoing reasons, we respectfully request that you reconsider the preliminary determination that the requested information is not required to be publicly disclosed. We further request that you clarify the timeline for searching other district offices and for full disclosure of all records requested in our FOIA request. We look forward to your prompt response.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Also on behalf of Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

Exh. A

ACLU
AMERICAN CIVIL LIBERTIES UNION of

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

January 4, 2011

Via Certified Mail, Return Receipt Requested

U.S. Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

Re: Request Under Freedom of Information Act—Expedited Processing

Dear FOIA Officer:

The American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) submit this expedited Freedom of Information Act (FOIA) request for records in the possession of the U.S. Food and Drug Administration (FDA) pertaining to the acquisition of controlled substances by state officials in California, Arizona, and other states for the purpose of carrying out executions of condemned prisoners by lethal injection. The ACLU-NC and the *Guardian* submit this request pursuant to the FOIA, 5 U.S.C. § 552, implementing regulations 21 C.F.R. 20.40 et. seq., 28 C.F.R. § 16.1 et. seq., and any other applicable regulations.

Records recently revealed by the California Department of Corrections (CDCR) indicate that the states of California, Arizona and Arkansas have imported controlled substances to be used in executions. These records reveal that these states were in direct communication with the FDA during 2010 regarding the importation of controlled substances, the procurement of controlled substances generally, and the requirements for transferring controlled substances between state corrections departments. The records disclosed by state officials raise serious questions about whether all applicable state and federal laws have been followed in the acquisition of controlled substances for the purpose of execution. The issue has generated widespread and exceptional media coverage, with 139 stories published in the last six months. Requesters are primarily engaged in disseminating information and there is a demonstrated urgency to inform the public concerning federal government activity.

AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA
39 DRUMM STREET, SAN FRANCISCO, CA 94111 | T/415.621.2493 | F/415.255.1478 | TTY/415.863.7832 | WWW.ACLUNC.ORG

I. Requested Records

We seek disclosure of agency records[1] in your[2] possession that fall within the following categories:

1. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

2. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the transfer between states of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

3. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

4. Records created since January 1, 2010, of internal communications within the FDA regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

5. Records created since January 1, 2010, of communications between any person at the FDA and any person outside the United States, including any official, employee or agent of any foreign government, regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

6. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of the U.S. Drug Enforcement Administration regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

7. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of U.S. Customs and Border Protection regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

---

[1] The term "records" as used herein includes all records or communications preserved in written or electronic form, including but not limited to: correspondence, documents, data, videotapes, audio tapes, emails, faxes, files, guidance, guidelines, evaluations, instructions, analyses, memoranda, agreements, notes, orders, policies, procedures, protocols, reports, rules, training materials, other manuals, or studies.

[2] Requestors seek records in the possession or control of the FDA office in Washington, D.C. and any field offices.

8. Records created since January 1, 2010, of communications between any person at the FDA and any private individual regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

9. Records created since January 1, 2010, regarding any actual importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

10. Records created since January 1, 2010, regarding any actual transfer of sodium thiopental, pancuronium bromide, and/or potassium chloride between state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

11. Records created since January 1, 2010, regarding any actual purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

12. Any policies, procedures, manuals, internal memorandum or other records regarding FDA procedures, policies, regulations or rules for the importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

II. Request for Expedited Processing

Title 5 U.S.C. § 552(a)(6)(E) provides for expedited processing of requests for information in cases in which the person requesting the records demonstrates a compelling need. By statute, for requests made by persons primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged federal government activity constitutes a "compelling need." 5 U.S.C. § 552(a)(6)(E)(v)(II). In addition, Department of Justice regulations state that FOIA requests are entitled to expedited processing when the information requested involves "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." 28 C.F.R. § 16.5(d)(1)(iv).

FDA regulations specifically provide for expedited processing, when "[w]ith respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." 21 C.F.R. § 20.44(a)(2). The FDA regulations further state:

> A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:
>
> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c).

Here, the requestors of this information are primarily engaged in disseminating information and, for reasons made clear below, there is urgency to inform the public concerning how state officials have acquired and are currently acquiring controlled substances to use in executions, and the role of federal officials in this process.[3] State officials are currently seeking to move forward with executions using controlled substances obtained from outside the United States and to acquire more of the lethal drugs. The value of the information to the public will be lost if not obtained and disseminated quickly, before additional executions occur using drugs of questionable origin and efficacy. FDA and other Federal government officials have been directly involved in the acquisition by state officials of controlled substances for purposes of execution. The acquisition of controlled substances for use in execution has been widely reported, caused widespread anxiety, and raised widespread concerns about potential misconduct by state and federal government officials.

1. Requestors.

The American Civil Liberties Union of Northern California (including the ACLU Foundation of Northern California), is an affiliate of the ACLU, a national organization that works to protect the civil liberties of all people, including the safeguarding of the basic constitutional rights to privacy, free expression, and due process of law. The ACLU-NC is responsible for serving the

[3] In 2006, a federal court ordered the Department of Defense to comply with a request for expedited processing request by the ACLU-NC and the *Guardian*. *ACLU-NC, et. al. v. Dept. of Defense*, 2006 WL 1469418, Case No. 06-01698 (N.D. Cal. May 25, 2006). *See also American Civil Liberties Union v. Dept. of Defense*, 339 F.Supp. 2d 501 (S.D.N.Y. 2004) (setting schedule for disclosure of documents to ACLU under expedited processing request).

population of northern California. The communications department of the ACLU-NC is the division of the ACLU-NC that is responsible for disseminating information to the public about issues of concern to the ACLU-NC and to the general public.

The *San Francisco Bay Guardian* is the largest circulation newsweekly in northern California, with an audited weekly distribution of 100,000. The paper is locally owned, independent, and has been published continuously since 1966.

2. Particular Value That Will Be Lost.

As documented in the news articles below, states including California and Arizona are actively and aggressively seeking to carry out executions of condemned inmates by lethal injection using controlled substances obtained from outside the United States. The origin, legality and efficacy of these controlled substances remain very much in question. The public has an urgent need to know where these lethal drugs came from, what they are, how well they work, and how they got into the country. There is a particular and unique value of this information to the public that will be lost if not obtained and disseminated quickly, before another state is allowed to carry out an execution using controlled substances obtained from outside the United States.

3. Widespread Media Interest and Concerns Regarding Federal Government Activities.

Since May 2010, there has been extensive news coverage around the country about how state officials are acquiring the controlled substances used in executions. More than 139 separate stories have been published, appearing in hundreds of media outlets in the United States and internationally. The issue has been covered by the largest media outlets, including the Associated Press, New York Times, Wall Street Journal, USA Today, Christian Science Monitor, CNN, MSNBC, and NPR. This widespread media attention demonstrates the public interest and concern over the potential for improper government activity in the acquisition of these controlled substances which are lethal and dangerous drugs.[4]

In May, 2010, media outlets began reporting that one of the controlled substances commonly used in executions in the United States, sodium thiopental, was unavailable due to production problem with the only FDA-approved, domestic supplier of the drug, Hospira. Soon after this was revealed, media outlets began reporting that the shortage of sodium thiopental was resulting in delays in executions in some states.

> *See* Andrew Welsh-Huggins, "Worldwide shortage of death penalty drug threatened upcoming Ohio execution," Associated Press, May 11, 2010 (Appendix A, Tab 1); Michael Kiefer, "Drug shortage may imperil executions in Arizona," Arizona Republic, May 17, 2010 (Appendix A, Tab 2); Jessie Hallady, "Anesthesia shortage may delay executions," USA Today, August 28, 2010 (Appendix A, Tab 3); Lucile Malandain, "Lethal drug supply dries up, postponing US executions," Agence France-Presse, September 4, 2010 (Appendix A, Tab 4); Julie Kent, "US States to Postpone Executions as Lethal Drug Runs Out," Cleveland Ledger, September 5, 2010 (Appendix A, Tab 5);

[4] The news articles mentioned in this letter are attached hereto as Appendix A.

Kathy Lohr, "States Delay Executions Owing To Drug Shortage," NPR All Things Considered, September 16, 2010 (Appendix A, Tab 6); Andrew Welsh-Huggins, "Some US executions held up by shortage of drug," Associated Press, September 28, 2010 (Appendix A, Tab 7); Mike Ward, "Drug shortage threatens executions, but not in Texas," Austin American Statesman, September 28, 2010 (Appendix A, Tab 8); Mike Tolson, "Drug shortage delays some executions, but not in Texas," Houston Chronicle, September 28, 2010 (Appendix A, Tab 9); Kevin Sack, "Shortage of Widely Used Anesthetics Is Delaying Executions in Some States," New York Times, September 29, 2010 (Appendix A, Tab 10); "Drugs shortage halts US executions," UK Associated Press, September 29, 2010 (Appendix A, Tab 11).

As the shortage began to impact executions, attorneys, community members and journalists began asking questions and expressing concern over how state corrections officials would obtain sodium thiopental, whether government officials would violate any state or federal law in their effort to obtain the drug, the efficacy of the drugs in their possession, and what other steps officials might take in order to proceed with executions.

See Michael Baker, "Federal judge issues stay of execution for Oklahoma death row inmate," Oklahoman, August 18, 2010 (Appendix A, Tab 12); Al Tompkins, "States Deal with Impact of Death Penalty Drug Shortage," Poynter, August 26, 2010 (Appendix A, Tab 13); Claudia Coffey, "Ky. governor holding off on some executions due to shortage of key drug," WHAS11.com, August 26, 2010 (Appendix A, Tab 14); Michael Baker, "Shortage of death penalty drug in Oklahoma delays executions," Oklahoman, September 13, 2010 (Appendix A, Tab 15); Lucile Malandain, "Drug shortage throws US executions into disarray," Agence France-Presse, October 25, 2010 (Appendix A, Tab 16); "Arkansas supplied drug used in recent Oklahoma execution," Associated Press, November 8, 2010 (Appendix A, Tab 17); Rina Palta, "Inside the evolving market for lethal injection drugs," KALW Informant, November 9, 2010 (Appendix A, Tab 18); Nathan Koppel, "New Execution Drug Approved," Wall Street Journal, November 19, 2010 (Appendix A, Tab 19); Koppel, "The Sun Shines In Texas on Lethal Injection," Wall Street Journal, November 19, 2010 (Appendix A, Tab 20); Kathy Lohr, "Okla. considers using vet drug to execute inmate," NPR Morning Edition, November 19, 2010 (Appendix A, Tab 21); Mike Ward, "Texas has lethal drugs on hand to execute 39 condemned criminals," Austin American Statesman, November 19, 2010 (Appendix A, Tab 22); Kevin Horrigan, "Capital punishment: How will Missouri "lethally inject" if it runs out of a lethal drug?" St. Louis Today, November 21, 2010 (Appendix A, Tab 23); Sam Stanton and Denny Walsh, "Drug shortage stirs death penalty debate in the U.S. and beyond," Sacramento Bee, December 5, 2010 (Appendix A, Tab 24); "Oklahoma executes man using new drug combination," Associated Press, December 16, 2010 (Appendix A, Tab 25).

An execution in California scheduled for September 30, 2010, was delayed in part because the state's supply of sodium thiopental expired on October 1, and the state was unable to lawfully acquire a new supply of the controlled substance. The issue generated enormous media coverage in the state and nationally.

See Jesse McKinley and Malia Wollan, "Governor Postpones Execution in California," New York Times, September 27, 2010 (Appendix A, Tab 26); Michael Winter, "Drug shortage prompts Calif. to suspend executions after Sept. 30," USA Today, September 27, 2010 (Appendix A, Tab 27); Howard Mintz, "Execution drama unfolds in California," San Jose Mercury News, September 27, 2010 (Appendix A, Tab 28); Jesse McKinley and Malia Wollan, "Judges Cancels California Execution," New York Times, September 28, 2010 (Appendix A, Tab 29); CNN Wire Staff, "Court ruling may stall California execution," CNN, September 28, 2010 (Appendix A, Tab 30); Paul Elias, "Court orders hearing for condemned Calif. Inmate," Associated Press, September 28, 2010 (Appendix A, Tab 31); Carol Williams, "California's first execution in five years delayed by legal issues," Los Angeles Times, September 28, 2010 (Appendix A, Tab 32); Sam Stanton, "Death penalty reprieve ordered," Sacramento Bee, September 28, 2010 (Appendix A, Tab 33); Bob Egelko, "Court sends execution case back to U.S. judge," San Francisco Chronicle, September 28, 2010 (Appendix A, Tab 34); Julia Cheever, "Appeals Court Orders Federal Judge To Reconsider Stay Of Execution Request For San Quentin Inmate," Bay City News, September 28, 2010 (Appendix A, Tab 35); Paul Elias, "Fed judge blocks Calif. execution set for Thursday," Associated Press, September 29, 2010 (Appendix A, Tab 36); Paul Elias, "Calif execution try collapses after court setbacks," Associated Press, September 29, 2010 (Appendix A, Tab 37); Howard Mintz, "With time running out, judge blocks execution," San Jose Mercury News, September 29, 2010 (Appendix A, Tab 38); Kevin Fagan, "Execution: Expiration date near for death drug," San Francisco Chronicle, September 29, 2010 (Appendix A, Tab 39); Denny Walsh, "Federal judge halts scheduled Thursday execution," Sacramento Bee, September 29, 2010 (Appendix A, Tab 40); Carol Williams, "Judge halts execution of rapist-murderer," Los Angeles Times, September 29, 2010 (Appendix A, Tab 41); Vauhini Vara and Nathan Koppel, "Spotlight on Injection Drug as Judge Stays Execution," Wall Street journal, September 30, 2010 (Appendix A, Tab 42); Jack Leonard and Victoria Kim, "California Supreme Court ends legal battle over execution," Los Angeles Times, September 30, 2010 (Appendix A, Tab 43); Denny Walsh and Sam Stanton, "State drops effort to execute rapist-murderer by today," Sacramento Bee, September 30, 2010 (Appendix A, Tab 44); Howard Mintz, "No Executions in '10," San Jose Mercury News, September 30, 2010 (Appendix A, Tab 45); Julia Cheever, "Supreme Court Blocks Execution Of San Quentin Man, Schwarzenegger Decries Decision," Bay City News, September 30, 2010 (Appendix A, Tab 46).

At the end of September, the state of Arizona suddenly acquired a new supply of sodium thiopental. The state eventually revealed that it had imported the sodium thiopental from the United Kingdom, but did not explain how it had imported the drug despite the fact that federal law prohibits importation of controlled substances from sources that are not approved by the FDA. The origin and legality of the Arizona drug became the focus of an intense legal battle with extensive local, national and international media coverage.

See "Arizona says it may get drug needed for execution," Associated Press, September 23, 2010 (Appendix A, Tab 47); Michael Kiefer, "Arizona Supreme Court puts execution on hold," Arizona Republic, September 24, 2010 (Appendix A, Tab 48); Michael Kiefer, "Arizona death row inmate's lawyers want drug info from state," Arizona

Republic, October 15, 2010 (Appendix A, Tab 49); James Clark, "Some Call it Murder: Breaking the Law in the Name of Capital Punishment," Change.org, October 15, 2010 (Appendix A, Tab 50); Paul Davenport, "Arizona execution caught in drug supply debate," October 19, 2010 (Appendix A, Tab 51); Michael Kiefer, "Judge asks Arizona for execution-drug source," Arizona Republic, October 21, 2010 (Appendix A, Tab 52); "Ariz. inmate files suit challenging execution drug," Associated Press, October 21, 2010 (Appendix A, Tab 53); John Schwartz, "Use of Drug Challenged in Death Penalty Case," New York Times, October 23, 2010 (Appendix A, Tab 54); Michael Kiefer, "Arizona told to reveal source of drug for execution," Arizona Republic, October 23, 2010 (Appendix A, Tab 55); John Schwartz, "Arizona: Drug Question Holds Up Execution," New York Times, October 25, 2010 (Appendix A, Tab 56); Paul Davenport, "Judge blocks Arizona execution, state appeals," Associated Press, October, 25, 2010 (Appendix A, Tab 57); "Inmate's lawyers ask judge to discuss drug info," Associated Press, October 25, 2010 (Appendix A, Tab 58); "State ordered to reveal info about drug for execution use," Associated Press, October 25, 2010 (Appendix A, Tab 59); "Arizona submits info on execution drugs to judge," Associated Press, October 25, 2010 (Appendix A, Tab 60); "Judge puts off Arizona execution, saying state not forthcoming," CNN, October 25, 2010 (Appendix A, Tab 61); Michael Kiefer, "Judge to question whether Arizona illegally obtained lethal-injection drug," Arizona Republic, October 25, 2010 (Appendix A, Tab 62); "Brewer Denies Delay In Landrigan Execution," KPHO-TV, October 25, 2010 (Appendix A, Tab 63); James Clark, "Sudden Secrecy Surrounds Death Penalty Drugs," Change.org, October 25, 2010 (Appendix A, Tab 64); Michael Kiefer, "Judge delays execution set for today," Arizona Republic, October 26, 2010 (Appendix A, Tab 65); "US execution blocked in row over lethal drug source," Agence France-Presse, October 26, 2010 (Appendix A, Tab 66); George Miller, "Inmate delays execution through drug-source protest," Fierce Pharma Manufacturing, October 26, 2010 (Appendix A, Tab 67); John Schwartz, "Murderer executed in Arizona," New York Times, October 27, 2010 (Appendix A, Tab 68); Nina Totenberg, "Supreme Court OKs Foreign Lethal Injection Drug," NPR, October 27, 2010 (Appendix A, Tab 69); "State Goes Overseas For Lethal Injection Drug," Associated Press, October 27, 2010 (Appendix A, Tab 70); "Arizona convicted killer's last words: 'Boomer Sooner,'" CNN, October 27, 2010 (Appendix A, Tab 71); Michael Kiefer, "Arizona executes inmate after federal judge lifts stay," Arizona Republic, October 27, 2010 (Appendix A, Tab 72); "Arizona executes man after Supreme Court green light," Agence France-Presse, October 27, 2010 (Appendix A, Tab 73); David Savage, "Justice Elena Kagan's first vote is against an execution," Los Angeles Times, October 27, 2010 (Appendix A, Tab 74); Victoria Ward, "Arizona execute man with drug supplied by British company," Telegraph, October 27, 2010 (Appendix A, Tab 75); Chris McGreal, "Arizona execution goes ahead after stay lifted," Guardian, October 27, 2010 (Appendix A, Tab 76); Rina Palta, "What the Arizona execution means for the death penalty nationwide," KALW Informant, October 27, 2010 (Appendix A, Tab 77); Tony Mauro, "High Court Split Paves Way for Arizona Execution," National Law Journal, October 28, 2010 (Appendix A, Tab 78); Joan Biskupic and Kevin Johnson, "Justices not convinced by arguments to delay execution," USA Today, October 28, 2010 (Appendix A, Tab 79); George Miller, "Report: Archimedes anesthetic used in Arizona execution," Fierce Pharma Manufacturing, October 28, 2010 (Appendix A, Tab 80).

Although Arizona was able to carry out one execution using the controlled substance imported from the United Kingdom, the action was criticized and continues to raise serious legal questions. The Arizona Supreme Court subsequently delayed an execution due to questions about the origin and efficacy of the drug.

> *See* Dahlia Lithwick, "Lethal Deflection," Slate.com, October 28, 2010 (Appendix A, Tab 81); New York Times Editorial, "No Justification," October 29, 2010 (Appendix A, Tab 82); James Clark, "Jeffrey Landrigan Executed by Arizona Amid Continued Secrecy," Change.org, October 30, 2010 (Appendix A, Tab 83); "Lawyer files complaint over British execution drug," Agence France-Presse, November 19, 2010 (Appendix A, Tab 84); Michael Kiefer, "Arizona Supreme Court puts off date for execution," Arizona Republic, December 1, 2010 (Appendix A, Tab 85).

On October 6, 2010, the California Department of Corrections and Rehabilitation disclosed that it too had recently obtained 12 grams of sodium thiopental, with an expiration date of 2014, despite the nationwide shortage. The CDCR did not disclose the source of the drug or explain how it came into possession of the scare substance. Because the last supply of sodium thiopental produced by Hospira has an expiration date of 2011, the sodium thiopental in the CDCR's possession could not have been manufactured domestically.

> *See* Carol Williams, "State has enough sodium thiopental to execute four," Los Angeles Times, November 8, 2010 (Appendix A, Tab 86); "Drug issue stalls executions in California," UPI, November 8, 2010 (Appendix A, Tab 87); Julie Small, "Corrections chief promises to divulge how California secured lethal injection drug," KPCC, November 19, 2010 (Appendix A, Tab 88); James Clark, "State refuses to give up lethal drug dealer," Change.org, November 22, 2010 (Appendix A, Tab 89).

The ACLU-NC filed a request under the California Public Records Act (PRA) to get records regarding the CDCR's acquisition of sodium thiopental. The *Guardian*, the Village Voice and the Associated Press also filed PRA requests seeking the records. Because the CDCR failed to respond to any of these requests, the ACLU-NC subsequently filed suit to enforce the PRA request, resulting in a court order that forced the CDCR to disclose the records.

> *See* Rina Palta, "ACLU: Where did California get its execution drugs?" KALW Informant, November 18, 2010 (Appendix A, Tab 90); Ryan Gabrielson, "ACLU sues state over lethal injection drug," California Watch, November 19, 2010 (Appendix A, Tab 91); Carol Williams, "State ordered to reveal source of its lethal-injection drug," Los Angeles Times, December 2, 2010 (Appendix A, Tab 92); Julie Small, "California prison officials ordered to disclose information on lethal injection drug," KPCC, December 2, 2010 (Appendix A, Tab 93); Rina Palta, "Judge: California must make execution drug records public," KALW Informant, December 2, 2010 (Appendix A, Tab 94).

The day before releasing the records to the ACLU-NC, the CDCR disclosed to selected journalists that it had ordered 521 grams of sodium thiopental manufactured by a company in the

United Kingdom and that the state paid more than $36,000 to acquire the drug. The CDCR told the journalists that the controlled substance had arrived in the United States but was currently in the procession of the FDA awaiting inspection.

> *See* Paul Elias, "Calif gets supply of drug used during executions," Associated Press, December 6, 2010 (Appendix A, Tab 95); Rina Palta, "Where California got its execution drugs," KALW Informant, December 6, 2010 (Appendix A, Tab 96); Paul Elias, "San Quentin gets supply of drug used during executions," Associated Press, December 7, 2010 (Appendix A, Tab 97); Sam Stanton, "Execution drug came from UK, CA officials say," Sacramento Bee, December 7, 2010 (Appendix A, Tab 98); Carol Williams, "California now has enough drugs to execute 175 death row inmates," Los Angeles Times, December 7, 2010 (Appendix A, Tab 99); "California buys execution drug from Britain," Agence France-Presse, December 7, 2010 (Appendix A, Tab 100); Rula Al-Nasrawi, "Secrets of the state's death-drug deal," San Francisco Bay Guardian, December 7, 2010 (Appendix A, Tab 101); Julie Small, "Prisons release details of lethal injection drug acquisition," KPCC-FM, December 8, 2010 (Appendix A, Tab 102); James Clark, "California reveals its drug dealer," Change.org, December 8, 2010 (Appendix A, Tab 103); "California Bought Scarce Lethal-Injection Drug From British Firm," Crime Report, December 8, 2010 (Appendix A, Tab 104); "CA Waiting For Lethal Injection Drug Approval," Corrections.com, December 8, 2010 (Appendix A, Tab 105).

The CDCR produced 980 pages of records regarding the acquisition of execution drugs to the ACLU-NC on December 8, 2010. The ACLU-NC posted the documents to its website the same day. Since posting, the page has been visited 2,213 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website. The records are available at:

> http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response_to_aclu_public_records_act_request.shtml.

The records disclosed by the CDCR raise serious questions about the conduct of state and federal government officials, and raise concern that state and federal laws were violated by the states' recent acquisition of sodium thiopental and by exchanges of controlled substances between different states. The information revealed in the records generated widespread media coverage in California, nationally and internationally.

> *See* Julie Small, "California's Corrections Department swapped lethal drugs with Arizona," KPCC, December 8, 2010 (Appendix A, Tab 106); George Miller, "Fierce Pharma Mfg - Imported death penalty drug to be tested by FDA," Fierce Pharma Manufacturing, December 8, 2010 (Appendix A, Tab 107); Paul Elias, "Docs show Calif.'s worldwide execution drug search," Associated Press, December 9, 2010 (Appendix A, Tab 108); Paul Elias, "Calif. scrambled for execution drug," Associated Press, December 9, 2010 (Appendix A, Tab 109); Rina Palta, "Timeline: California's scramble for execution drugs," KALW Informant, December 9, 2010 (Appendix A, Tab 110); Natasha Minsker, "I've got a secret mission for you," ACLU Blog of Rights,

December 9, 2010 (Appendix A, Tab 111); Jeff Neumann, "Arizona prison officials called 'life savers' for sharing lethal drug," Gawker.com, December 9, 2010 (Appendix A, Tab 112); Mike Ward, "California: Texas officials turned down request for execution drug," Statesman.com, December 9, 2010 (Appendix A, Tab 113); David Usborne, "Emails reveal gallows humour on death row," Independent, December 10, 2010 (Appendix A, Tab 114); Christopher Brauchli, "The executioner's drugs," Counter Punch, December 10, 2010 (Appendix A, Tab 115); Anthony Lydgate, Weekly Review, Harper's Magazine, December 14, 2010 (Appendix A, Tab 116); "Mysteries of the death-drug scramble," *San Francisco Bay Guardian*, December 14, 2010 (Appendix A, Tab 117); Ryan Gabrielson, "State withholds name of lethal drug supplier," California Watch, December 17, 2010 (Appendix A, Tab 118).

See also The Colbert Report, Tiny Triumphs—Lethal Drug Shortage, available at: http://www.colbertnation.com/the-colbert-report-videos/368731/december-15-2010/tiny-triumphs---lethal-drug-shortage?xrs=share_copy

In addition, the fact that state officials have been importing sodium thiopental from the United Kingdom has generated significant public outcry, legal challenges, and media attention, both in the United Kingdom, and in the United States. Following disclosure that states in the U.S. were acquiring execution drugs from sources in the UK, the government of the United Kingdom imposed new restrictions preventing the export of sodium thiopental for purposes of execution.

See Clive Stafford Smith, "The British company making a business out of killing," Guardian, October 26, 2010 (Appendix A, Tab 119); Owen Bowcott and Chris McGreal, "British firm denies exporting drug for Arizona execution," Guardian, October 27, 2010 (Appendix A, Tab 120); Robert Verkaik, "British company link to drug used in execution," Independent, October 27, 2010 (Appendix A, Tab 121); Michael Seamark, "British company denies exporting drug used in US execution after Arizona's supplies run dry," Daily Mail, October 28, 2010 (Appendix A, Tab 122); Ian Dunt, "Cable under fire for allowing execution drug sale," Politics.com, November 2, 2010 (Appendix A, Tab 123); David Cronin, "Not Executing, Just Enabling, IPS News, November 4, 2010 (Appendix A, Tab 124); Paddy, McGuffin, "Cable in court over death drug export," UK Morning Star, November 17, 2010 (Appendix A, Tab 125); "Cable attacked on 'execution drug.'" UK Press Associated, November 17, 2010 (Appendix A, Tab 126); John Aston, "Bid to ban export of 'execution' drug," Independent, November 17, 2010 (Appendix A, Tab 127); Benjamin Timmins, "British imposes controls on lethal injection drug," Associated Press, November 29, 2010 (Appendix A, Tab 128); Clive Stafford Smith, "A welcome U-turn from Vince Cable on execution drug," Guardian, November 29, 2010 (Appendix A, Tab 129); Michael Kiefer, "Controls imposed on lethal injection drug Arizona uses," Arizona Republic, November 29, 2010 (Appendix A, Tab 130); Dominic Casciani, "US lethal injection drug faces UK export restrictions," BBC, November 29, 2010 (Appendix A, Tab 131); Peter Walker, "Vince Cable restricts export of drug used in US executions," Guardian, November 29, 2010 (Appendix A, Tab 132); Daily Mail Reporter, "Human rights victory as Vince Cable imposes restrictions," November 29, 2010 (Appendix A, Tab 133); Tim Edwards, "Cable restricts export of lethal injection drug to US," First Post, November 29, 2010 (Appendix A, Tab 134);

Nathan Koppel and Jeanne Whalen, "U.K. Limits Execution Drug's Export," Wall Street Journal, November 30, 2010 (Appendix A, Tab 135); "U.K. to limit export of execution drug widely used in U.S.," MSNBC, November 30, 2010 (Appendix A, Tab 136); James Clark, "America's death penalty looses and ally," Change.org, November 30, 2010 (Appendix A, Tab 137); Mark Townsend, "US execution drugs supplied secretly by British companies," Guardian, December 19, 2010 (Appendix A, Tab 138); Paddy McGuffin, "Lethal drugs secretly shipped to California," UK Morning Star, December 19, 2010 (Appendix A, Tab 139).

As the forgoing demonstrates, questions about how state officials are acquiring controlled substances to use in executions and the role of federal officials in that process have generated exceptional, widespread media coverage in the United States and across the globe. The issue raises substantial questions about the integrity of government, at the state and federal level. The public has an urgent need for additional information as state officials continue to pursue new acquisitions of controlled substances for executions and seek to use substances in their possession of questionable origin and efficacy. The particular value of this information to the public will be lost if not obtained and disseminated quickly. For these reasons, the FDA should grant expedited processing of this FOIA request.

III. "Public Interest" Fee Waiver Request

We request a waiver of document search, review, and duplication fees on the grounds that disclosure of the requested records is in the public interest because disclosure is "likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." *See* 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. 20.46(a); see also 28 C.F.R. § 16.11(k)(1).

The FDA regulations further specify that the FDA will consider the following factors when determining if disclosure is in the public interest:

> (1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;
>
> (2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;
>
> (3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

> (4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

All of these factors are met here. First, the records sought pertain to the role of the FDA and other government officials in facilitating the acquisition by state officials of controlled substances for the purpose of execution. Second, disclosure of the records would reveal significant information that is currently unknown, specifically the details of how state officials acquired non-FDA approved controlled substances from outside the United States. Third, disclosure will assist the public generally in understanding a critical aspect of the capital punishment process in the United States and the requesters are in a position to disseminate the information broadly, as detailed below. Fourth, contributing to the public's understanding of the capital punishment process is a substantial and weighty public interest.

The requestors plan to disseminate widely to the public records disclosed as a result of this FOIA request. The ACLU-NC's communications department is a division of a nonprofit 501(c)(3) organization, and both the ACLU-NC's communications department and the *Guardian* are "representative[s] of the news media." They are well situated to disseminate information gained through this request to the public, to affected communities and to political and legal organizations. The requestors routinely obtain information about government activity (including through FOIA), analyze that information, and widely publish and disseminate that information to the press and to the public in a variety of ways including the following:

The ACLU-NC's communications department disseminates information through the website, http://www.aclunc.org, which had 477,995 page views in 2010. This website addresses civil liberties issues in depth and provides features on civil liberties issues on which the ACLU-NC is focused. As noted, the ACLU-NC posted the documents obtained from the CDCR regarding the acquisition of execution drugs on the day it received the records, December 8, 2010. Since posting, the page has been visited 2,835 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website.

The ACLU-NC's communications department also publishes reporters, news briefings, right-to-know documents, and other materials that are disseminated to the public. Its material is widely available to everyone, including tax-exempt organizations, not-for-profit groups, law students and faculty, for no cost. ACLU-NC staff persons are frequent spokespersons in television and print media and make frequent public presentations at meetings and events. Finally, the ACLU-NC's communications department disseminates information through a newsletter, which is distributed to subscribers by mail. Due to these extensive publication activities, the ACLU-NC is a "representative of the news media" under the FOIA and agency regulations.

As noted, the *Guardian* is the largest circulation newsweekly in northern California, with audited weekly distribution of 100,000 copies. The paper covers breaking news, does detailed investigative reporting, publishes editorials and covers arts, entertainment, and lifestyle issues. The *Guardian* has received more than 100 state, local and national awards for journalistic

excellence. The *Guardian* is a member of the California Newspaper Publishers Association and the Association of Alternative Newsweeklies.

Finally, disclosure of the requested records is not in the requestors' commercial interest. See 21 C.F.R. § 20.46(c). The records requested are not sought for commercial use and the ACLU-NC plans to disseminate the information disclosed as a result of this FOIA request to the public at no cost. Thus, a fee waiver would fulfill Congress's legislative intent in amending FOIA. *See Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be 'liberally construed in favor of waivers for noncommercial requesters.'") (citation omitted).

IV. News Media Status Fee Limitation Request

We also request a waiver of document search and reproduction fees on the grounds that the requestors qualify as "representatives of the news media" and the records are not sought for commercial use. 21 C.F.R. § 20.45(a)(2). The *Guardian* is a newsweekly. The ACLU-NC also meets the statutory and regulatory definitions of a "representative of the news media" because they are "entit[ies] that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." 5 U.S.C. § 552(a)(4)(A)(ii); *see also Nat'l Sec. Archive v. Dep't of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989) (finding that an organization that "gathers information from a variety of sources," exercises editorial discretion in selecting and organizing documents, "devises indices and finding aids," and "distributes the resulting work to the public" is a "representative of the news media" for purposes of the FOIA); *cf. ACLU v. Dep't of Justice*, 321 F. Supp. 2d at 30 n.5 (finding non-profit public interest group to be "primarily engaged in disseminating information").[5]

Notably, courts have found other organizations whose missions, functions, publishing, and public education activities are similar in kind to the ACLU's to be "representatives of the news media." *See, e.g., Elec. Privacy Info. Ctr. v. Dep't of Defense*, 241 F. Supp. 2d 5, 10-15 (D.D.C. 2003) (finding non-profit public interest group that disseminated an electronic newsletter and published books was a "representative of the media" for purposes of FOIA); *Nat'l Security Archive*, 880 F.2d at 1387; *Judicial Watch, Inc. v. Dep't of Justice*, 133 F. Supp. 2d 52, 53-54 (D.D.C. 2000) (finding Judicial Watch, self-described as a "public interest law firm," a news media requester).[6]

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[5] Fees associated with responding to FOIA requests are regularly waived for the ACLU, and a number of agencies have determined that the ACLU is a "representative of the news media" for the purposes of FOIA, including the Departments of Justice, State, and Commerce. In December 2008, the Department of Justice found that the ACLU was a "representative of the news media" for the purposes of FOIA in the context of a request for documents relating to the detention, interrogation, treatment, or prosecution of suspected terrorists.

[6] Courts have founds these organizations to be "representatives of the news media" even though they engage in litigation and lobbying activities beyond their dissemination of information/public education activities. *See, e.g., Elec. Privacy Info. Ctr.*, 241 F. Supp. 2d 5; *Nat'l Sec. Archive*, 880 F.2d at 1387; *see also Judicial Watch, Inc.*, 133 F. Supp. 2d at 53-54; *see also Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 260 (D.D.C. 2005) (finding Leadership Conference to be primarily engaged in disseminating information even though it engages in substantial amounts of legislative advocacy beyond its publication and public education functions).

* * *

If this request is denied in whole or in part, we ask that you justify all withholdings by reference to specific exemptions to the FOIA. We expect the release of all segregable portions of otherwise exempt material. If the fee waivers are denied, the requesters are prepared to pay fees up to $100, and request to be informed of further fees that may be charged, but reserve the right to appeal a denial of fee waivers.

Thank you for your prompt attention to this matter. Please furnish all applicable records to Natasha Minsker, American Civil Liberties Union of Northern California, 39 Drumm Street, San Francisco, California 94111, telephone (415) 621-2493, email nminsker@aclunc.org.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

Certification

Pursuant to 21 C.F.R. § 20.44(d), I, Natasha Minsker, certify that the information in this request is true and correct to the best of my knowledge and belief.

January 4, 2011

Signed in San Francisco, California

Natasha Minsker

Exh. B

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

March 31, 2011

American Civil Liberties Union of Northern California
Attn: Natasha Minsker
39 Drumm St.
San Francisco, CA 94111

Dear Requestor: Refer to FOI # F11-319

We apologize for the delay. This is in response to your request of January 4, 2011 for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding: importation of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

Enclosed are the records you requested:

- 7 Page transmittal for entry 574-0251126-5 including: CBP Form 3461- 1 Page, Letter from AZ Dept of Corrections dated September 24, 2010- 1 Page, Dream Pharma invoices- 2 Pages, and 3 Pages of DEA registration (one page of carrier air bill not included).

- 8 Page transmittal for entry 574-0250322-1 including: CBP Form 3461- 1 Page, Dream Pharma invoice- 1 Page, CBP form 7512- 1 Page, 2 letters from AZ Dept of Corrections- 2 Pages, DEA registration – 2 Pages, Dream Pharma invoice- 1 Page.

- Email, subject: Completed conference with Dan…- 2 Pages

- DEA registration- 1 Page

- Email, subject: Dream Pharma Shipments- 2 Pages

- Email, subject: Entry 574-0250322-1: Lethal Injection Pharmacology- 3 Pages

- Email, subject: FW: Entry number of 9/29/10 shipment- 2 Pages

- Email, subject: FW: Lethal injection pharmacology entry 574-0251126-5 – 5 Pages

- OASIS report for entry 574-0250322-1 dated 09/29/2010 – 1 Page

- OASIS report for entry 574-0251126-5 dated 01/07/2011 – 2 Pages

- OASIS screen printout for 574-0251126-5 – 1 Page

- Email, subject: Update Your Pharmaceutical Entry – 1 Page

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have to right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges for this request to date may be included in a monthly invoice:

/ace

Reproduction	Search	Review	Fiche	Other	Total
$ 3.50	$ 23.00	$ 46.00	$ 00.00	$ 00.00	$ 72.50

The above total may not reflect final charges for this request. Please *do not* send payment unless you receive an invoice.
All communications concerning this request should be identified with the referenced number above and addressed as follows:

Food and Drug Administration
Division of Freedom of Information, HFI-35
OPILS/OSS/DFOI
12430 Parklawn Drive, Room 1050
Rockville, MD 20857

Sincerely,

John Bryce
Analyst
Los Angeles District

cc: _X_ HFI-35
_X_ Please Assess Charges
____ No Purging Necessary

/ace

Exh. C

Bryce, John *

From: Thomas, David
Sent: Wednesday, October 27, 2010 12:19 PM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: FW: Lethal Injection pharmacology entry 574-0251126-5

Importance: High

Attachments: 574-0251126-5.pdf

Daniel:

Attached is the original email and documentation of the last of 2 entries.

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Thomas, David
Sent: Tuesday, October 26, 2010 8:47 AM
To: Batista, Huascar R
Cc: Verbeten, John E. (ORA); Solis, Daniel; Strickland, Evanguel
Subject: Lethal Injection pharmacology entry 574-0251126-5
Importance: High

Husacar:

I have the same produot coming into Phoenix Port of entry 2605, Sodium Thiopental, imported by the same Arizona Department of Corrections (DOC), manufactured by the same oompany, Dream Pharma Ltd. The entry is for the same purpose, lethal injection pharmacology.

Does the previous email notification, dated September 29, 2010, hold true for this shipment?

Please find attached entry documentation for the above.

574-0251126-5.
pdf (407 KB)

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----
From: Batista, Huascar R
Sent: Wednesday, September 29, 2010 10:35 AM
To: Thomas, David
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

Correct.

-----Original Message-----
From: Thomas, David
Sent: Wednesday, September 29, 2010 1:33 PM
To: Batista, Huascar R
Cc: Solis, Daniel; Strickland, Evanguel; Verbeten, John E. (ORA); Notzon, Stella; Bormel, Frances Gail; Anderson, Kathleen R
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

Huascar:

I am in receipt of your communication, thank you. To confirm, CDER is not objecting to the release of the above entry of 3 pharmaceuticals from U.K.

Thank you for your timely reply. I will advise AZ DOC of the new FDA entry status.

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----
From: Batista, Huascar R
Sent: Wednesday, September 29, 2010 10:28 AM
To: Thomas, David
Cc: Solis, Daniel; Strickland, Evanguel; Verbeten, John E. (ORA); Notzon, Stella; Bormel, Frances Gail; Anderson, Kathleen R
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

(b) (5)

Huascar Batista
Imports & Exports Compliance Team Leader
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
WO-51, 5374
Silver Spring, MD 20993
Tel: 301.796.3411

-----Original Message-----
From: Thomas, David
Sent: Wednesday, September 29, 2010 12:57 PM
To: Verbeten, John E. (ORA); Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Solis, Daniel; Strickland, Evanguel
Subject: Entry 574-0250322-1: Lethal Injection Pharmacology
Importance: High

John:

The above entry of Lethal Injection pharmacology has been transmitted for the purpose of execution of a Arizona prisoner.

The issue involves 3 products from manufacturer Dream Pharma, London, UK, FEI 3004744216. Product 1) Thiopental Sodium NDC 000703-2556, product 2) Panouronium Bromide NDC 000074-4645, and product 3) Potassium Chloride Injectible NDC 000469-6520 do not appear to have valid DRLS numbers for the manufacturer. However, Dream Pharma is registered under the aforementioned FEI.

Arizona Department of Corrections Director, Charles Ryan, 602-542-5225, has related in previous correspondence that his agency must have these products in hand today to be accountable to the Arizona Supreme Court by September 30, 2010 for the intended purpose above. (see attached AZ DOC correspondence)

Currently the product is being trucked into Phoenix from Los Angeles. (b) (4) mistakenly routed the product from (b) (4) to Los Angeles, CA instead of the planned flight to Phoenix, AZ.

Lastly, I have attached the entry documentation and held the entry in my inbox, pending Agency approval of a release.

May I hear from you soon,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----
From: Verbeten, John E. (ORA)
Sent: Wednesday, September 29, 2010 3:54 AM
To: Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel
Subject: Re: Lethal Injection Pharmacology

(b) (5)

----- Original Message -----
From: Notzon, Stella
To: Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel; Verbeten, John E. (ORA)
Sent: Mon Sep 27 13:06:53 2010
Subject: FW: Lethal Injection Pharmacology

Huascar, et.al,

(b) (5)

Stella

-----Original Message-----
From: Thomas, David
Sent: Monday, September 27, 2010 11:33 AM
To: Notzon, Stella
Cc: Strickland, Evanguel; Solis, Daniel
Subject: FW: Lethal Injection Pharmacology
Importance: High

Stella:

FYI

Dave Thomas

FDA Imports
Phoenix, AZ

-----Original Message-----
From: Thomas, David
Sent: Monday, September 27, 2010 8:23 AM
To: Taube, Anthony C
Cc: Strickland, Evanguel; Solis, Daniel; 'DEAN, MICHAEL K'; 'CHARLES FLANAGAN'
Subject: Lethal Injection Pharmacology
Importance: High

Prior Notice Center Director, Anthony Taube:

RE: Lethal Injection pharmacology:

Sir:

I have an entry of 3 components of a lethal injection, 1) Thiopental, 2) Pancuronium, 3) Potassium Chloride departing London this afternoon, destination (b)(4) with Port of Entry 2605, Phoenix. As of this communication, no entry has been made.

These pharmaceuticals are needed to carry out an execution here in Arizona, and are not for public consumption. Attached is Please find attached explanatory documentation and DEA registration for the Arizona Corrections facility.

Lastly, should I be advising anyone else?

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

Charles:

We are in receipt of your communication and PDF attachments. I have CC'd my Supervisor, Mr. Strickland, and our Imports Director Mr. Solis for their review.

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----
From: CHARLES FLANAGAN [mailto:CFLANAG@azcorrections.gov]
Sent: Friday, September 24, 2010 5:04 PM
To: Thomas, David
Subject: Pharmaceuticals from Dream Pharma, LTD. of London, England

Good Afternoon Mr. Thomas:

Thank you so much for your assistance with this matter. I have attached to this email a copy of the correspondence what will be shipped with the pharmaceuticals. It also includes the Department of Corrections' "Substance Control Registration Certificate". The second attachment is a list of the items that will be shipped to our facility; to include quantities purchased and the last attachment is the revised DEA Registration which includes certification for Schedule 2 drugs.

Once again, thank you again for your assistance. Should you require additional information, please do not hesitate to contact me. Here is my information:

Charles Flanagan
Deputy Director
Arizona Department of Corrections

1601 W. Jefferson - MC 445
Phoenix, Arizona 85007
(602) 542-3611 Office
(602) 377-5334 Cell
(602) 364-0601 Fax
cflanag@azcorrections.gov

David Thomas, DCM
FDA Investigations
Phoenix, Office

Bryce, John *

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:37 PM
To: Strickland, Evanguel
Subject: Completed conference with Dan. Out of office at 3:30 PM

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 3:12 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: First entry scenario, complete

Thanks you. This is good.

Is there one for Entry # 574-0251126-5?

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:08 PM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: First entry scenario, complete

Daniel:

This is complete for the first entry.

Entry 574-0250322-1

September 24, 2010 Mr. Charles Flanagan, Deputy Director Arizona Department of Corrections (602) 542-3611 contacted CSO David Thomas from the FDA Office in Phoenix stating he wanted to import a shipment of drugs from overseas and asked the procedures. Mr. Flanagan was directed to U.S.C.B.P. for a list of brokers to choose from to initiate an importation process.

September 27 2010 [redacted] (b) (4) was chosen by AZ DOC. [redacted] (b) (4) sent PHX-RP imports partial entry information which included letter of intent, DEA certificate, and list of products. Products were Thiopental Sodium, Potassium Chloride, and Pancuronium Bromide. [redacted] (b) (4) also advised PHX-PR the entry 574-0250322-1 would be transmitted wheels up from the U.K. An email was sent to DIOP and supervision immediately notifying of the proposed import with attached documentation of the information received from [redacted] (b) (4) Entry review of manufacturer, Dream Pharma Ltd. of London, England revealed the manufacturer was FDA registered for certain drugs, but not the drugs being imported.

1. FDA Investigator was provided with an official letter from the Arizona Department of Corrections stating this shipment of drugs was warranted by the Arizona Supreme Court (State v. [redacted] (b) (6)
2. Manufacturer Dream Pharma has several FDA registration numbers for drugs; however not for

the aforementioned being imported.

3. Arizona Department of Corrections also has a DEA registration number (b) (7)(E)

September 29, 2010 entry arrived Port of Entry Phoenix via (b) (4)
PHX-RP received email notification from DIOP that entry was available for release. Upon arrival that afternoon, product was confirmed for labeling, count and amount with AZ DOC personnel in accompaniment of the CSO. Product was FDA released, then taken into custody by AZ DOC after the inspection.

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 2:55 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: Scenario Initial AZ DOC entry

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5

Notice Number: 1
January 7, 2011

Filer:
(b) (4)

Attention: (b) (4)
Broker Box: (b) (4)

>

<

Port of Entry: 2605, Phoenix, AZ
Carrier: (b) (4)
Date Received: October 25, 2010
Arrival Date: October 26, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002
Consignee: (b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	THIOPENTAL SODIUM, POWDER	(b) (4)	Released 01-06-2011

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry 574-0251126-5. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA	Product Description
001/001	THIOPENTAL SODIUM, POWDER

Comments : FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics.

Ruben Delagarza, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700

(310) 971-2297
(310) 971-2363 (FAX)
laimports@FDA.HHS.GOV

Notice of FDA Action
Entry Number: 574-0251126-5

Notice Number 1
Page: 2

San Pedro, CA 90731

LINES RELEASED

Line ACS/FDA	Product Description
001/001	THIOPENTAL SODIUM, POWDER

Ruben Delagarza, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700
San Pedro, CA 90731

(310) 971-2297
(310) 971-2363 (FAX)
laimports@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: JRB

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

Form Approved
OMB No. 1651-0024
Exp. 01-31-2012

ENTRY/IMMEDIATE DELIVERY

(b) (4)

(b) (4)

000 BOX #

19 CFR 142.3, 142.16, 142.22, 142.24

ABI CERTIFIED

1. ARRIVAL DATE	2. ELECTIS ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
102610		11 INFORMAL -	574-0251126-5
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
2605	X891	(b) (4)	
	8. CONSIGNEE NUMBER		**9. IMPORTER NUMBER**
	(b) (4)		(b) (4)
10. ULTIMATE CONSIGNEE NAME		**11. IMPORTER OF RECORD NAME**	
(b) (4)		PHOENIX, AZ 85007-3002	
12. CARRIER CODE	**13. VOYAGE/FLIGHT/TRIP**	**14. LOCATION OF GOODS-CODE/NAME**	
	(b) (4)	(b) (4) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	**17. MANIFEST NUMBER**	**18. B/L NUMBER**	**19. TOTAL VALUE**
2605			1246

20. DESCRIPTION OF MERCHANDISE
MEDICAL EQUIPMENT

21. IT/AUAWS CODE	22. IT/AUAWS NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.
M	12562148505	1	3004909130	GB	GBDREPHA176LON

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF A
X ATTY-
PHONE NO. 1-
Fax#:1-

(b) (4)

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

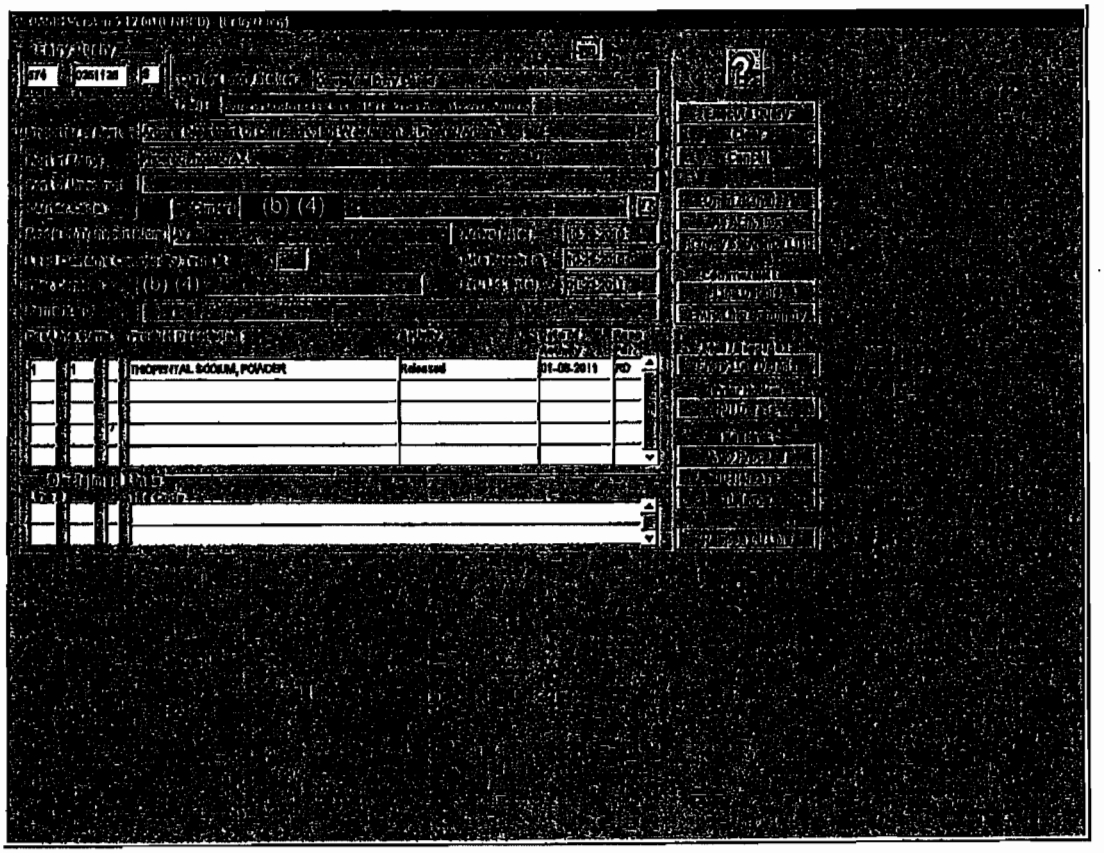
DELIVERY AUTHORIZED:	SIGNATURE	DATE

Exam Site: (b) (4)

Paperwork Reduction Act Statement: An agency may not conduct or sponsor an information collection and a person is not required to respond to this information unless it displays a current valid OMB control number and an expiration date. The control number for this collection is 1651-0024. The estimated average time to complete this application is 15 minutes. If you have any comments regarding the burden estimate you can write to U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., Washington DC 20229.

PX/3461 (1/10) PART 1 CBP Form 3461 (10/09)

T'd (b) (4) [redacted] 08 26 2010 8:17AM


(b) (4)
(b) (4)
Released
01-08-2011
PO

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 22-10-2010

Address:
Arizona State Prison Complex - Florence
(b) (4)

Delivery Address:
(b) (4)

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED
"This is not for use by the general public"

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection powder for reconstitution, thiopental sodium, [redacted] mg vial packs of [redacted] Batch No: (b) (4) 3004.90.9130	[redacted]	(b) (4)	[redacted]

Shipping Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total: [redacted] GBP - Pounds sterling
	Payment Method: Prepayment Thank You

1-582[illegible]
1245.75

Shipping Details

Packing: ONE BOX 39X30X27CM	Gross Weight (Kg): 8.75
Tariff: 30049099	Net Weight (Kg): 3.1875
	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd.

DREAM PHARMA LTD 176 Horn Lane Acton London W3 6PJ Tel: 020 8992 7000

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

p.2 (b) (4) [redacted] 8:17AM 26 2010 Sep

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 22-10-2010

Address:
Arizona State Prison Complex - Florence
(b) (4)

Delivery Address:
(b) (4)

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Shipping charges for invoice number (b) (4)	[redacted]	[redacted]	[redacted]

Statement of Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing:	Gross Weight (Kg): Net Weight (Kg): 0
Tariff: 30049099	Carrier (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd. DREAM PHARMA LTD 176 Horn Lane W3 6PJ Tel: 020 8992 7000 Fax: 020 8992 7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

p.3 (b) (4) (b) (4) Oct 26 2010 8:17AM

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1

Notice Number: 1
September 29, 2010

Filer:
(b) (4)

Attention: (b) (4)
Broker Box: (b) (4)

>

Port of Entry: 2605, Phoenix, AZ
Carrier: (b) (4)
Date Received: September 29, 2010
Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002
Consignee: (b) (4)

<

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	THIOPENTAL SODIUM 500 MG	(b) (4)	Released 09-29-2010
002/001	PANCURONIUM INJECTION		Line Split
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE		Released 09-29-2010

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry 574-0250322-1. Any status changes are reflected in the Line summary and line detail sections.

David C. Thomas, Investigator
U.S. Food & Drug Administration
51 W. 3rd Street, Suite E-265
Tempe, AZ 85281

(480) 829-7396 ext. 12
(480) 829-7677 (FAX)
DAVID.THOMAS@FDA.HHS.GOV

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: JRB

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

Form Approved
OMB No. 1651-0024

ENTRY/IMMEDIATE DELIVERY

(b) (4)

POD. BOX #

19 CFR 142.3, 142.16, 142.22, 142.24

ABI Certified

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
092810	092810	01 Consump	874-0250322-1

5. PORT	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER
2605	1891	(b) (4)

8. CONSIGNEE NUMBER	8. [illegible]
(b) (4)	(b) (4)

10. [illegible]
(b) (4)

11. IMPORTER OF RECORD NAME
ARIZONA DEPARTMENT OF CORRECTIONS
1601 W. JEFFERSON ST
PHOENIX, AZ 85007-3002

12. CARRIER CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS CODE/NAME
(b) (4)	000	(b) (4)

15. VESSEL CODE/NAME

16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. B/L NUMBER	19. TOTAL VALUE
(b) (4)			(b) (4)

20. DESCRIPTION OF MERCHANDISE
THIOPENTAL, POTASSIUM, PANCURONI

21. LINE ITEM NO.	22. ITEM/HTS NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	COUNTRY	26. MANUFACTURER NO.
H	8721364B1249	1	30049091.30	GB	GBDREPHA176LON
I	2004310185		2933394100	GB	GBDREPHA176LON
M	0235B499140		3104200000	GB	GBDREPHA176LON

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate; the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE
X (b) (4)
PHONE

28. BROKER OR OTHER GOVT. AGENCY USE

CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

Pharmacy Program Manager

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:	SIGNATURE	DATE

Exam Site: (b) (4)

Dream Pharma Ltd.

176 Harri Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 . Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details
Number: INV0000
Date: 29-09-2010

Address:
(b) (4)

Delivery Address:
(b) (4)

004.94.9130/Fax
104.20.0000/6,5%
3-2733.37.4100/Fax

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

1	[illegible] (b) (4)	[illegible]	(b) (4)	(b) (4)
2	[illegible] (b) (4)			
3	[illegible] (b) (4)			

Statement Details

512,516,433.47

Goods total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (Import Duty): 0.00
Delivery: [illegible]	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: ONE BOX	Gross Weight (Kgs): 25
Total Packages:	Net Weight (Kgs): 17.00
Declaration: We certify that this invoice is true and correct.	Carrier: (b) (4)
	Mail Address: [illegible]

[illegible]

SEP.29.2010 9:38AM NO.867 P.4/9

19 CFR 10.60, 10.61, 123.41, 123.42

Entry No. _____
Port _____
Date _____

TRANSPORTATION ENTRY AND MANIFEST OF GOODS SUBJECT TO CBP (INSPECTION AND PERMIT U.S. Customs and Border Protection

OMB No. 1651-0003 Exp. 12-31-2010

Entry No. 200510185
Class of Entry I.T. 61
(I.T.) (T.E.) (WD.IE) (Drawback, etc.)

PORT CODE NO [redacted] FIRST U.S. PORT OF UNLADING (b) (4) [redacted]

PORT OF (b) (4) [redacted] DATE 29SEP10

Entered or imported by (b) (4) [redacted] Importer/IRS # (b) (4) [redacted] to be shipped

In bond via (b) (4) [redacted] (C.H.L number) (Vessel or carrier) (Car number and initial) (Pier or station) consigned to

CBP Port Director PHOENIX, AZ 2605 Final foreign destination _____ (For exportations only)

Consignee [redacted] (b) (4) [redacted] (At CBP port of exit or destination)

Foreign port of lading _____ B/L No. (b) (4) [redacted] Date of sailing _____
(Above information to be furnished only when merchandise is imported by vessel)

Imported on the (b) (4) [redacted] Flag USA on 28SEP10 via STN
(Name of vessel or carrier and native power) (Date imported) (Last foreign port)

Exported from UNITED KINGDOM (Country) on 28SEP10 (Date) Goods now at (b) (4) [redacted] (Name of warehouse, station, pier, etc.)

Marks and Numbers of Packages	Description and Quantity of Merchandise Number and Kind of Packages (Describe fully as per shipping papers)	Gross Weight in Pounds	Value (Dollars only)	Rate	Duty
1 PCS	872136481249 PHARMACEUTICALS NOT RESTRICTED THIOPENTAL INJECTION POWDER FOR RECONSTITUTION THIOPENTAL SODIUM [redacted]- MG VIAL PACKS OF (b) (4) BATCH NO [redacted] 05%.4 POTASSIU *** BROKER INFORMATION *** [redacted] (b) (4) [redacted] CONTACT [redacted]	ESTIMATED NOT VERIFIED [redacted]	(b) (4) [redacted] USD		

G.O. No. _____ ☐ Check if withdrawn for Vessel supplies (19 U.S.C. 1309)

CERTIFICATE OF LADING FOR TRANSPORTATION IN BOND AND/OR LADING FOR EXPORTATION FOR

PHOENIX, AZ 2605 (Port)

WITH THE EXCEPTIONS NOTED ABOVE, THE WITHIN-DESCRIBED GOODS WERE:

Delivered to the Carrier named above, for delivery to the CBP Port Director at destination sealed with CBP seals Nos. WAIVED or the packages (were) (were not) labeled, or corded and sealed.

AMS AUTHORIZED (Inspector) _____ (Date)

Laden on the— _____ (Vessel, vehicle, or aircraft)
which cleared for— _____
on _____ (Date)
as verified by export records.
_____ (Inspector) _____ (Date)

I truly declare that the statements contained herein are true and correct to the best of my knowledge and belief.
Entered or withdrawn by _____
(b) (4) [redacted]
EMP# (b) (4) [redacted]

To the Inspector: The above-described goods shall be disposed of
AMS AUTHORIZED
For the Port Director

Received from the Port Director of the above CBP location the merchandise described in this manifest for transportation and delivery into the custody of the CBP officers at the port named above, all packages in apparent good order except as noted hereon.
(b) (4) [redacted]
Emp# (b) (4) [redacted]
Attorney or Agent of Carrier

CBP Form 7512 (03/08)

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 28-09-2010

Address:
(b) (4)
85232

Delivery Address:
(b) (4)

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, [redacted] mg vial packs of [redacted] Batch No: (b) (4)	[redacted]	(b) (4)	(b) (4)
POTASSIUM CHLORIDE 1.5GM [redacted] INJ. PACKS OF [redacted] Batch No: (b) (4)	[redacted]	(b) (4)	(b) (4)
Pancuronium Injection, pancuronium bromide 2 mg/mL, [redacted] mL amp packs of [redacted] Batch No: (b) (4) [redacted]	[redacted]	(b) (4)	(b) (4)
Special delivery charges	[redacted]	[redacted]	[redacted]

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: [redacted]	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: ONE BOX	Gross Weight (Kg): 25 Net Weight (Kg): 21.25
Tariff: 30049099	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd

DREAM PHARMA LTD
176 Horn Lane
Acton, London W3 6PJ
Tel: 020-8992-7000
Fax: 020-8992-7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: (b) (4) VAT No (b) (4)
Director: M. Alavi

Exh. D

SEP.29.2010 9:38AM NO.867 P.4/9

19 CFR 10.60, 10.61, 123.41, 123.42

Entry No.
Port
Date

TRANSPORTATION ENTRY AND MANIFEST OF GOODS SUBJECT TO CBP INSPECTION AND PERMIT

U.S. Customs and Border Protection

OMB No. 1651-0003 Exp. 12-31-2010

Entry No. 200610185
Class of Entry I.T. 61
(I.T.) (T.E.) (WD,IE) (Drawback, etc.)

PORT CODE NO [redacted] FIRST U.S. PORT OF UNLADING (b) (4)

PORT OF (b) (4) DATE 29SEP10

Entered or imported by (b) (4) Importer/IRS # (b) (4) to be shipped

In bond via (b) (4) (C.H.L. number) (Vessel or carrier) (Car number and initial) (Pier or station) consigned to

CBP Port Director PHOENIX, AZ 2605 Final foreign destination (For exportations only)

Consignee (b) (4) (AICBP port of exit or destination)

Foreign port of lading B/L No. (b) (4) Date of sailing
(Above information to be furnished only when merchandise is imported by vessel)

Imported on the (b) (4) (Name of vessel or carrier and motive power) Flag USA on 29SEP10 (Date imported) via STN (Last foreign port)

Exported from UNITED KINGDOM (Country) on 28SEP10 (Date) Goods now at (b) (4) (Name of warehouse, station, pier, etc.)

Marks and Numbers of Packages	Description and Quantity of Merchandise Number and Kind of Packages (Describe fully as per shipping papers)	Gross Weight in Pounds	Value (Dollars only)	Rate	Duty
1 PCS	872136481249 PHARMACEUTICALS NOT RESTRICTED THIOPENTAL INJECTION POWDER FOR RECONSTITUTION THIOPENTAL SODIUM (b) (4)- MG VIAL PACKS OF (b) (4) BATCH NO [redacted] (b) (4) 05%4 POTASSIU *** BROKER INFORMATION *** [redacted] (b) (4) [redacted] CONTACT [redacted]	ESTIMATED NOT VERIFIED [redacted]	(b) (4) USD		

G.O. No. ☐ Check if withdrawn for Vessel supplies (19 U.S.C. 1309)

CERTIFICATE OF LADING FOR TRANSPORTATION IN BOND AND/OR LADING FOR EXPORTATION FOR

PHOENIX, AZ 2605 (Port)

WITH THE EXCEPTIONS NOTED ABOVE, THE WITHIN-DESCRIBED GOODS WERE:

Delivered to the Carrier named above, for delivery to the CBP Port Director at destination sealed with CBP seals Nos. WAIVED or the packages (were) (were not) labeled, or corded and sealed.

AMS AUTHORIZED (Inspector)

(Date)

Laden on the-- (Vessel, vehicle, or aircraft)

which cleared for--

on (Date)

as verified by export records.

(Inspector)

(Date)

I truly declare that the statements contained herein are true and correct to the best of my knowledge and belief.

Entered or withdrawn by (b) (4)

EMP# (b) (4)

To the Inspector: The above-described goods shall be disposed of

AMS AUTHORIZED
For the Port Director

Received from the Port Director of the above CBP location the merchandise described in this manifest for transportation and delivery into the custody of the CBP officers at the port named above, all packages in apparent good order except as noted hereon.

(b) (4)

EMP# (b) (4)
Attorney or Agent of Carrier

CBP Form 7512 (03/08)

Exh. E

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

Form Approved
OMB No. 1651-0024
Exp. 01-31-2012

ENTRY/IMMEDIATE DELIVERY

(b) (4) (b) (4)

(b) (4)

000 BOX #

19 CFR 142.3, 142.16, 142.22, 142.24

ABI CERTIFIED

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
102610		11 INFORMAL -	574-0251126-5
5. PORT	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER	
2605	X891	(b) (4)	
	8. CONSIGNEE NUMBER		9. IMPORTER NUMBER
	(b) (4)		(b) (4)
10. ULTIMATE CONSIGNEE NAME & ADDRESS		11. IMPORTER OF RECORD NAME & ADDRESS	
(b) (4)		PHOENIX, AZ 85007-3002	
12. CARRIER CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS CODE/NAME(S)	
	(b) (4)	(b) (4) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. S.C. NUMBER	19. TOTAL VALUE
2605			1246

20. DESCRIPTION OF MERCHANDISE
MEDICAL EQUIPMENT

21. IT&E/AWB CODE	22. IT&E/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.
M	12562148505	1	3004909130	GB	GBDREPHA176LON

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF A
X ATTY-
PHONE NO. 1-
Fax#:1-

(b) (4)

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:	SIGNATURE	DATE

Exam Site: (b) (4)

Paperwork Reduction Act Statement: An agency may not conduct or sponsor an information collection and a person is not required to respond to this information unless it displays a current valid OMB control number and an expiration date. The control number for this collection is 1651-0024. The estimated average time to complete this application is 15 minutes. If you have any comments regarding the burden estimate you can write to U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., Washington DC 20229.

FX/3461 (1/10) PART 1 CBP Form 3461 (10/09)

I-d (b) (4) DEC 28 2010 8:17AM

Exh. F

Bryce, John *

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:37 PM
To: Strickland, Evanguel
Subject: Completed conference with Dan. Out of office at 3:30 PM

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 3:12 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: First entry scenario, complete

Thanks you. This is good.

Is there one for Entry # 574-0251126-5?

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:08 PM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: First entry scenario, complete

Daniel:

This is complete for the first entry.

Entry 574-0250322-1

September 24, 2010 Mr. Charles Flanagan, Deputy Director Arizona Department of Corrections (602) 542-3611 contacted CSO David Thomas from the FDA Office in Phoenix stating he wanted to import a shipment of drugs from overseas and asked the procedures. Mr. Flanagan was directed to U.S.C.B.P. for a list of brokers to choose from to initiate an importation process.

September 27 2010 [redacted] (b) (4) was chosen by AZ DOC.
(b) (4) sent PHX-RP imports partial entry information which included letter of intent, DEA certificate, and list of products. Products were Thiopental Sodium, Potassium Chloride, and Pancuronium Bromide. (b) (4) also advised PHX-PR the entry 574-0250322-1 would be transmitted wheels up from the U.K. An email was sent to DIOP and supervision immediately notifying of the proposed import with attached documentation of the information received from (b) (4) Entry review of manufacturer, Dream Pharma Ltd. of London, England revealed the manufacturer was FDA registered for certain drugs, but not the drugs being imported.

1. FDA Investigator was provided with an official letter from the Arizona Department of Corrections stating this shipment of drugs was warranted by the Arizona Supreme Court (State v. [redacted] (b) (6)
2. Manufacturer Dream Pharma has several FDA registration numbers for drugs; however not for

Exh. G

the aforementioned being imported.

3. Arizona Department of Corrections also has a DEA registration number (b) (7)(E)

September 29, 2010 entry arrived Port of Entry Phoenix via (b) (4)
PHX-RP received email notification from DIOP that entry was available for release. Upon arrival that afternoon, product was confirmed for labeling, count and amount with AZ DOC personnel in accompaniment of the CSO. Product was FDA released, then taken into custody by AZ DOC after the inspection.

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 2:55 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: Scenario initial AZ DOC entry

ACLU
AMERICAN CIVIL LIBERTIES UNION of

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

May 10, 2011

Deputy Assistant Secretary for Public Affairs (Media)
U.S. Department of Health and Human Services
7700 Wisconsin Ave., Suite 920
Bethesda, MD 20857

Re: FOIA Appeal, Reference # 2011-319 and 2011-2661

Dear Deputy Assistant Secretary:

Requestors American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) write to appeal the Food and Drug Administration's (FDA) decision not to provide us with the information we requested under the Freedom of Information Act (FOIA), identified by the FDA as FOIA Request # 2011-319 and 2011-2661.

On January 4, 2011, we requested records pertaining to the acquisition of controlled substances by state officials for the purpose of carrying out executions of condemned prisoners by lethal injection. In our request, ACLU-NC and the *Guardian* sought the release of twelve categories of information pertaining to the importation, transfer, or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution. *See* Exh. A (FOIA Request dated January 4, 2011). On January 19, 2011 (the January 19 documents) and February 8, 2011 (the February 8 documents), we received records from the New Orleans District Office of the Food and Drug Administration. These records were heavily redacted and we requested reconsideration of the redactions.

On April 20, 2011, we received via email 117 pages of records accompanied by a letter from Frederick J. Sadler, Director of the Division of Freedom of Information, dated April 11, 2011 (the April 11 documents).[1] Mr. Sadler's letter, attached as Exhibit B, states that the FDA has "completed its processing" of our FOIA request and cites various statutory exemptions as

[1] On April 19, Natasha Minsker of the ACLU-NC called Sara Kotler of the FDA to enquire about the status of Requestors' request for reconsideration of redactions because we had received no response as of that date. Ms. Kotler responded in a phone message that the documents had been placed in the mail on "April 11 or April 12" and that she would look into the matter. On April 20, at Ms. Kotler's request, Theola Myo Khin emailed the documents and letter dated April 11 to Ms. Minsker. To date, we have not received the documents via US mail.

authority for denying portions of our request. The April 11 documents consist largely of records already released to us from the New Orleans District Office, with fewer redactions.[2]

We write to appeal the agency's decision to withhold the redacted information and the failure to release all relevant documents in the agency's possession, pursuant to 45 C.F.R. § 5.34. We believe the FOIA exemptions cited by the FDA do not apply to the records we requested. We also believe such records should be released regardless of whether the exemptions apply in light of the FDA's submission of administrative records in *Beaty v. FDA*, No. 1:11-cv-00289 (D.D.C. filed Feb. 2, 2011). We further believe that the agency has failed to adequately search for responsive records and that additional records are in the agency's possession that should be released.

We incorporate by reference our previous letter to the FDA dated February 15, 2011 (the February 15 letter), attached as Exhibit C, which further explains our objections to the redactions.

1. **Agency Has Inappropriately Redacted Information the Public Has a Right to View**

A. Redactions Pursuant to 5 U.S.C. § 552(b) and Related Regulations

The FDA cites the following exemptions under FOIA as authority for denying us access to the requested information:

- 5 U.S.C. § 552(b)(4), trade secret and confidential commercial information; and
- 5 U.S.C. § 552(b)(7)(C), records or information compiled for law enforcement purposes when disclosure could reasonably be expected to constitute an unwarranted invasion of personal privacy.

Exh. B. The FDA does not expressly claim that any other sections of the FOIA statute justify the redactions, but the redactions to the April 11 documents appear implicitly to rely on two additional exemptions:

- 5 U.S.C. § 552(b)(5), certain interagency and intra-agency communications; and
- 5 U.S.C. § 552(b)(6), information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy.

[2] We also received records from the main office of the FDA on March 21, 2011 and the Los Angeles District Office on March 31, 2011; we have requested reconsideration of the redactions in the Los Angeles records. Mr. Sadler's April 11 letter makes no mention of the Los Angeles District Office or the records released from that office.

If the redactions labeled (b)(5) and (b)(6) were made erroneously, we request that the redacted information be restored. If the redactions were intended but omitted from the FDA's letter, we dispute the applicability of these exemptions.

The FDA relies upon the (b)(4) exemption primarily as authority to redact the price and quantity of imported sodium thiopental. The FDA also relies upon (b)(4) in redacting the names of importers, transportation information such as flight numbers, and receiving party addresses. As we explained in our February 15 letter, such price and quantity information is not confidential commercial or financial information, nor is it a trade secret. *See* Exh. C. Similarly, the names of business entities, state corrections departments, and flight numbers are not trade secrets or confidential commercial information. In the FOIA context, courts have adopted a restrictive definition of "trade secret," limiting it to a "secret, commercially valuable plan, formula, process, or device" that is the "end product of either innovation or substantial effort." *Public Citizen Health Research Group v. Food and Drug Administration*, 704 F.2d 1280, 1288 (D.C. Cir. 1983). Names and transportation information are not plans, formulas, processes, or devices, nor are they the result of innovation. Therefore, they are not trade secrets. Nor are they confidential commercial information; it would be difficult for a company to do business if its name were confidential.

The implementing regulations support our conclusion that exemption (b)(4) does not apply to the information we seek. As the FDA's letter indicates, the regulations relating to (b)(4) are 45 C.F.R. § 5.65 and 21 C.F.R. § 20.61(c). These regulations mirror the language of *Public Citizen Health Research Group* in the definition of "trade secret," and of *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974), in the definition of "confidential." We discussed both of these cases in our February 15 letter, explaining that these cases mandate disclosure of the redacted information. We do not repeat that discussion here but incorporate it by reference. Finally, 45 C.F.R. § 5.65 protects "privileged" information that "would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege." We do not believe that the price, quantity, names of organizations, and flight information at issue would be ordinarily protected from such disclosure.

The Drug Enforcement Administration (DEA) appears to agree with our understanding of exemption (b)(4). The DEA recently released a small set of records to us in response to a similar FOIA request, seeking records related to efforts by states to import controlled substances to use in executions. These records contain the name of the company that imported sodium thiopental for the California Department of Corrections and Rehabilitation, a company by the name of Chemique Pharmaceuticals, based in Whittier, California. Given that the DEA understands that this information is properly disclosed under FOIA, we request that FDA reconsider its position.

FOIA exemption (b)(7)(C) is referenced interchangeably with exemption (b)(6) throughout the April 11 documents as the basis for redacting signatures and identifying information of individuals and/or organizations. Although (b)(6) is not cited as authority in the FDA's letter, it is used more frequently than (b)(7)(C). In some cases, (b)(6) is used as authority where (b)(7)(C) was used in a previous release of documents. *See, e.g.*, Exh. D, Comparison of

Fax from Georgia Department of Corrections dated August 10, 2010 (comparing fax as released April 11, citing (b)(6), and fax as released February 8, citing (b)(7)(C)). The use of different exemptions for the same or substantially similar information suggests that the agency itself is not sure which exemption applies and why. We submit that neither exemption applies, especially where the exemptions are used to withhold the names of (1) government officials who may be involved in official misconduct or (2) business relationships where the information does not implicate a particular business actor in a crime. Such disclosures are not unwarranted invasions of privacy. *See* Exh. C; *Lissner v. U.S. Customs Service*, 241 F.3d 1220, 1223 (9th Cir. 2001); *Center to Prevent Handgun Violence v. U.S. Department of Treasury*, 981 F. Supp. 20, 23-24 (D.D.C. 1997).

The implementing regulations for (b)(7)(C), cited in the FDA's letter, are 45 C.F.R. § 5.68(c) and 21 C.F.R. § 20.64(a)(3).[3] These regulations state that the FDA is careful not to disclose information that could reasonably be expected to constitute an unwarranted invasion of personal privacy. For the reasons explained above, we disagree that providing the requested information would constitute an unwarranted invasion of privacy.

The FDA also cites (b)(5) as an exemption in an email from Christopher Boulmay, an FDA officer, to John McAuliffe of the California Department of Corrections and Rehabilitation, dated November 30, 2010. This redaction is also inconsistent with redactions in prior releases by the FDA, which we noted in our February 15 letter. Exh. C.

Furthermore, different exemptions and redactions are applied to the same, or closely analogous, information within the April 11 documents. For example, in an email from John McAuliffe to Christopher Boulmay dated November 30, 2010, the name of a FedEx contact person is redacted pursuant to (b)(6). Just a few pages earlier the exact same information in the same email was left unredacted. Exh. E, Comparison of Email from John McAuliffe dated November 30, 2010. Another example is the Dream Pharma invoices. In some invoices, the receiving party, delivery address, and total cost of the shipment are redacted under (b)(4), while in others, all of this information is disclosed. Exh. F, Dream Pharma Invoices. Inconsistent redactions of other communications between state and federal government entities, FedEx, and Dream Pharma abound: sometimes the total cost is redacted and sometimes it is not. This uneven treatment of cost data shows that the exemptions were improperly applied.

B. Redactions Pursuant to Other Laws

In addition to FOIA exemptions and implementing regulations, the FDA also indicates that other laws may prohibit disclosure of the information we requested. Specifically, the agency's letter refers to the Federal Trade Secrets Act, 18 U.S.C. § 1905, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(j). The Trade Secrets Act provision prohibits federal employees from disclosing any information relating to "trade secrets, processes, operations" and

[3] The letter also refers to 21 C.F.R. § 514.11(e)(c)(3)(vi), which does not exist. Section 514.11 is related to confidentiality of data in a new animal drug application file and appears to be cited in error.

similar information. 18 U.S.C. § 1905. The Food, Drug, and Cosmetic Act provision prohibits any person from revealing or using to his advantage any trade secrets that are entitled to protection. As explained above, none of the redacted information constitutes a trade secret.

C. Records Submitted in *Beaty v. FDA*

On April 20, 2011, the FDA submitted 70 pages of administrative records to the District of Columbia District Court in *Beaty v. FDA*. While there is some overlap between the materials released in response to our FOIA request and those submitted in *Beaty*, a substantial number of documents in *Beaty* are either less redacted than or entirely excluded from the documents the FDA sent to us. The documents submitted in *Beaty* demonstrate that the agency has excessively and inappropriately redacted the documents provided to us. Just one example is a letter from Benjamin Rice of California to Ruth Dixon of the FDA, dated December 9, 2010: in the documents we received, the quantity of sodium thiopental is redacted under (b)(4), but in the *Beaty* records, the letter is entirely unredacted, showing that the California Department of Corrections and Rehabilitation had ordered 521 grams of thiopental. Exh. G, Comparison of Letter from Benjamin Rice dated December 9, 2010 (comparing letter as submitted in *Beaty* and letter as released to us on April 11). Clearly, this data is not a trade secret or confidential commercial information because the FDA has released it in public court records, demonstrating that no FOIA exemptions apply to such records.

2. FDA Has Not Searched Exhaustively and Has Not Produced All Disclosable Records

The documents filed by the FDA in *Beaty* further demonstrate that the FDA has failed to exhaustively search for and disclose to us all relevant public records in its possession. For example, the FDA filed the following the records in the *Beaty* case, yet failed to produce these same records to us:

- Email message printed from the account of Julie Dohm with the subject "Import Bulletin #60-B08," regarding importation of sodium thiopental. *See* Exh H.
- Email message printed from the account of Julie Dohm with the subject "assistance on sodium thiopental question raised by UK Embassy," and letter attached to the email from the British Embassy to the U.S. State Department. *See* Exh. I.
- Two additional emails from the account of Julie Dohm, and one email from the account of Merly Ramos, all communication with the British government regarding the use of sodium thiopental in the US. *See* Exh J.
- A letter from the Arizona Department of Corrections to the FDA, dated November 10, 2010, regarding one of its shipments of imported execution drugs. *See* Exh K.
- A document entitled "Sodium Thiopental Statement, Key Messages," and dated December 29, 2010. *See* Exh L.

- An email printed from the account of Julie Dohm, directed to Nathan Koppel, reporter with the Wall Street Journal, about the FDA's position on importation of sodium thiopental. *See* Exh M.

- A document entitled "Guidance for handling pending and future shipments of Sodium Thiopental," dated January 5, 2011. *See* Exh N.

- Documents related to the inspection of a plant in Austria that apparently has or does manufacture sodium thiopental. *See* Exh O.

All of these records fall squarely within our FOIA request and should have been produced. The contents of the documents indicate that additional records exist that have not yet seen the light of day. For example, in the "Key Messages" document, the FDA states that it has released imported sodium thiopental to state prisons, "consistent with the agency's longstanding policy." Our FOIA requests specifically sought documents related to any such policy, yet none have been produced. The same document asserts that FDA "reviewed its procedures for the importation of sodium thiopental in concert with CBP [Customs and Border Protection]." Although we specifically requested documents related to that "review," none have been produced. The document also states that the agencies "are working together to develop a system for future shipments." Again, none of the records produced to us reflect this work, or the existence of any such system. Likewise, the document entitled "Guidance for handling for handling pending and future shipments of Sodium Thiopental," states "Compliance Policy Guide need to be written," and "Reports will be generated… ." The FDA failed to produce any records related to a policy guide or any reports on the imported sodium thiopental.

In addition, the FDA has failed to produce a complete set of documents for any of the shipments of sodium thiopental known to have entered the US in the last year. From media accounts, we know that eight states have imported controlled substances for executions: six states imported from Dream Pharma in the UK (Arizona, Arkansas, California, Georgia, South Carolina, and Tennessee) and two imported from Kayem Pharmaceutical in India (Nebraska and South Dakota). The FDA has failed to provide any records at all related to the Nebraska and South Dakota shipments.

Further, a comparison of the records produced for each shipment from Dream Pharma reveals eight different documents that should exist for each shipment:

Notice of FDA Action (at least one if not multiple)
Entry/Immediate Delivery Form
Invoice
Manifest
Airbill
DEA Registration Form
FDA OASIS database entries

Department of Treasury Forms F-698

A comparison of the records produced for each of the Dream Pharma shipments reveals the following records are still missing:

- Arizona (2 shipments)
  Entry/Immediate Delivery Forms
  Manifests
  Airbills
  FDA OASIS database entries
  Department of Treasury Forms F-698

- Arkansas
  DEA Registration Form
  FDA OASIS database entry
  Department of Treasury Form F-698

- California
  DEA Registration Form
  Manifest
  FDA OASIS database entry

- Georgia
  DEA Registration Form
  FDA OASIS database entry
  Department of Treasury Form F-698

- South Dakota
  DEA Registration Form
  FDA OASIS database entry
  Department of Treasury Form F-698

- Tennessee
  Notice of FDA Action
  DEA Registration Form
  FDA OASIS database entry
  Department of Treasury Form F-698

The FDA's response thus far falls far short of an exhaustive review and demonstrates, rather, a cursory and haphazard search for records.[4] We request that the FDA conduct a thorough search for all electronic and paper documents within the scope of our FOIA request, or provide an explanation as to why the missing records are exempt from disclosure.

* * *

For the foregoing reasons, we respectfully request that the FDA release all additional documents responsive to our requests and restore the material that has been improperly redacted. We look forward to your response within 20 business days, as required under 5 U.S.C. § 552(a)(6).

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Also on behalf of Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

[4] The documents discussed above are an illustrative not exclusive list of documents that should have provided pursuant to an adequate search.

Exh. A

ACLU
AMERICAN CIVIL LIBERTIES UNION of

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

January 4, 2011

Via Certified Mail, Return Receipt Requested

U.S. Food and Drug Administration
Division of Freedom of Information (HFI-35)
Office of Shared Services
Office of Public Information and Library Services
5600 Fishers Lane
Rockville, MD 20857

Re: Request Under Freedom of Information Act—Expedited Processing

Dear FOIA Officer:

The American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) submit this expedited Freedom of Information Act (FOIA) request for records in the possession of the U.S. Food and Drug Administration (FDA) pertaining to the acquisition of controlled substances by state officials in California, Arizona, and other states for the purpose of carrying out executions of condemned prisoners by lethal injection. The ACLU-NC and the *Guardian* submit this request pursuant to the FOIA, 5 U.S.C. § 552, implementing regulations 21 C.F.R. 20.40 et. seq., 28 C.F.R. § 16.1 et. seq., and any other applicable regulations.

Records recently revealed by the California Department of Corrections (CDCR) indicate that the states of California, Arizona and Arkansas have imported controlled substances to be used in executions. These records reveal that these states were in direct communication with the FDA during 2010 regarding the importation of controlled substances, the procurement of controlled substances generally, and the requirements for transferring controlled substances between state corrections departments. The records disclosed by state officials raise serious questions about whether all applicable state and federal laws have been followed in the acquisition of controlled substances for the purpose of execution. The issue has generated widespread and exceptional media coverage, with 139 stories published in the last six months. Requesters are primarily engaged in disseminating information and there is a demonstrated urgency to inform the public concerning federal government activity.

AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA
39 DRUMM STREET, SAN FRANCISCO, CA 94111 | T/415.621.2493 | F/415.255.1478 | TTY/415.863.7832 | WWW.ACLUNC.ORG

I. Requested Records

We seek disclosure of agency records[1] in your[2] possession that fall within the following categories:

1. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

2. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the transfer between states of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

3. Records created since January 1, 2010, of communications between any person at the FDA and any state official, employee or agent regarding the purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

4. Records created since January 1, 2010, of internal communications within the FDA regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

5. Records created since January 1, 2010, of communications between any person at the FDA and any person outside the United States, including any official, employee or agent of any foreign government, regarding the importation from another country of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

6. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of the U.S. Drug Enforcement Administration regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

7. Records created since January 1, 2010, of communications between any person at the FDA and any official, employee or agent of U.S. Customs and Border Protection regarding the importation; transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

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[1] The term "records" as used herein includes all records or communications preserved in written or electronic form, including but not limited to: correspondence, documents, data, videotapes, audio tapes, emails, faxes, files, guidance, guidelines, evaluations, instructions, analyses, memoranda, agreements, notes, orders, policies, procedures, protocols, reports, rules, training materials, other manuals, or studies.

[2] Requestors seek records in the possession or control of the FDA office in Washington, D.C. and any field offices.

8. Records created since January 1, 2010, of communications between any person at the FDA and any private individual regarding the importation, transfer or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

9. Records created since January 1, 2010, regarding any actual importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

10. Records created since January 1, 2010, regarding any actual transfer of sodium thiopental, pancuronium bromide, and/or potassium chloride between state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

11. Records created since January 1, 2010, regarding any actual purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution, including but not limited to: any "Notice of FDA Action"; forms; declarations; attachments to any forms, notices or declarations; tracking records; photographs; communications of any kinds including any requests for exemption, expedited processing or other special treatment.

12. Any policies, procedures, manuals, internal memorandum or other records regarding FDA procedures, policies, regulations or rules for the importation of sodium thiopental, pancuronium bromide, and/or potassium chloride by state officials for the purpose of execution.

II. Request for Expedited Processing

Title 5 U.S.C. § 552(a)(6)(E) provides for expedited processing of requests for information in cases in which the person requesting the records demonstrates a compelling need. By statute, for requests made by persons primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged federal government activity constitutes a "compelling need." 5 U.S.C. § 552(a)(6)(E)(v)(II). In addition, Department of Justice regulations state that FOIA requests are entitled to expedited processing when the information requested involves "[a] matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity which affect public confidence." 28 C.F.R. § 16.5(d)(1)(iv).

FDA regulations specifically provide for expedited processing, when "[w]ith respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." 21 C.F.R. § 20.44(a)(2). The FDA regulations further state:

> A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:
>
> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c).

Here, the requestors of this information are primarily engaged in disseminating information and, for reasons made clear below, there is urgency to inform the public concerning how state officials have acquired and are currently acquiring controlled substances to use in executions, and the role of federal officials in this process.[3] State officials are currently seeking to move forward with executions using controlled substances obtained from outside the United States and to acquire more of the lethal drugs. The value of the information to the public will be lost if not obtained and disseminated quickly, before additional executions occur using drugs of questionable origin and efficacy. FDA and other Federal government officials have been directly involved in the acquisition by state officials of controlled substances for purposes of execution. The acquisition of controlled substances for use in execution has been widely reported, caused widespread anxiety, and raised widespread concerns about potential misconduct by state and federal government officials.

1. Requestors.

The American Civil Liberties Union of Northern California (including the ACLU Foundation of Northern California), is an affiliate of the ACLU, a national organization that works to protect the civil liberties of all people, including the safeguarding of the basic constitutional rights to privacy, free expression, and due process of law. The ACLU-NC is responsible for serving the

[3] In 2006, a federal court ordered the Department of Defense to comply with a request for expedited processing request by the ACLU-NC and the *Guardian. ACLU-NC, et. al. v. Dept. of Defense*, 2006 WL 1469418, Case No. 06-01698 (N.D. Cal. May 25, 2006). *See also American Civil Liberties Union v. Dept. of Defense*, 339 F.Supp. 2d 501 (S.D.N.Y. 2004) (setting schedule for disclosure of documents to ACLU under expedited processing request).

population of northern California. The communications department of the ACLU-NC is the division of the ACLU-NC that is responsible for disseminating information to the public about issues of concern to the ACLU-NC and to the general public.

The *San Francisco Bay Guardian* is the largest circulation newsweekly in northern California, with an audited weekly distribution of 100,000. The paper is locally owned, independent, and has been published continuously since 1966.

2. Particular Value That Will Be Lost.

As documented in the news articles below, states including California and Arizona are actively and aggressively seeking to carry out executions of condemned inmates by lethal injection using controlled substances obtained from outside the United States. The origin, legality and efficacy of these controlled substances remain very much in question. The public has an urgent need to know where these lethal drugs came from, what they are, how well they work, and how they got into the country. There is a particular and unique value of this information to the public that will be lost if not obtained and disseminated quickly, before another state is allowed to carry out an execution using controlled substances obtained from outside the United States.

3. Widespread Media Interest and Concerns Regarding Federal Government Activities.

Since May 2010, there has been extensive news coverage around the country about how state officials are acquiring the controlled substances used in executions. More than 139 separate stories have been published, appearing in hundreds of media outlets in the United States and internationally. The issue has been covered by the largest media outlets, including the Associated Press, New York Times, Wall Street Journal, USA Today, Christian Science Monitor, CNN, MSNBC, and NPR. This widespread media attention demonstrates the public interest and concern over the potential for improper government activity in the acquisition of these controlled substances which are lethal and dangerous drugs.[4]

In May, 2010, media outlets began reporting that one of the controlled substances commonly used in executions in the United States, sodium thiopental, was unavailable due to production problem with the only FDA-approved, domestic supplier of the drug, Hospira. Soon after this was revealed, media outlets began reporting that the shortage of sodium thiopental was resulting in delays in executions in some states.

> *See* Andrew Welsh-Huggins, "Worldwide shortage of death penalty drug threatened upcoming Ohio execution," Associated Press, May 11, 2010 (Appendix A, Tab 1); Michael Kiefer, "Drug shortage may imperil executions in Arizona," Arizona Republic, May 17, 2010 (Appendix A, Tab 2); Jessie Hallady, "Anesthesia shortage may delay executions," USA Today, August 28, 2010 (Appendix A, Tab 3); Lucile Malandain, "Lethal drug supply dries up, postponing US executions," Agence France-Presse, September 4, 2010 (Appendix A, Tab 4); Julie Kent, "US States to Postpone Executions as Lethal Drug Runs Out," Cleveland Ledger, September 5, 2010 (Appendix A, Tab 5);

[4] The news articles mentioned in this letter are attached hereto as Appendix A.

Kathy Lohr, "States Delay Executions Owing To Drug Shortage," NPR All Things Considered, September 16, 2010 (Appendix A, Tab 6); Andrew Welsh-Huggins, "Some US executions held up by shortage of drug," Associated Press, September 28, 2010 (Appendix A, Tab 7); Mike Ward, "Drug shortage threatens executions, but not in Texas," Austin American Statesman, September 28, 2010 (Appendix A, Tab 8); Mike Tolson, "Drug shortage delays some executions, but not in Texas," Houston Chronicle, September 28, 2010 (Appendix A, Tab 9); Kevin Sack, "Shortage of Widely Used Anesthetics Is Delaying Executions in Some States," New York Times, September 29, 2010 (Appendix A, Tab 10); "Drugs shortage halts US executions," UK Associated Press, September 29, 2010 (Appendix A, Tab 11).

As the shortage began to impact executions, attorneys, community members and journalists began asking questions and expressing concern over how state corrections officials would obtain sodium thiopental, whether government officials would violate any state or federal law in their effort to obtain the drug, the efficacy of the drugs in their possession, and what other steps officials might take in order to proceed with executions.

See Michael Baker, "Federal judge issues stay of execution for Oklahoma death row inmate," Oklahoman, August 18, 2010 (Appendix A, Tab 12); Al Tompkins, "States Deal with Impact of Death Penalty Drug Shortage," Poynter, August 26, 2010 (Appendix A, Tab 13); Claudia Coffey, "Ky. governor holding off on some executions due to shortage of key drug," WHAS11.com, August 26, 2010 (Appendix A, Tab 14); Michael Baker, "Shortage of death penalty drug in Oklahoma delays executions," Oklahoman, September 13, 2010 (Appendix A, Tab 15); Lucile Malandain, "Drug shortage throws US executions into disarray," Agence France-Presse, October 25, 2010 (Appendix A, Tab 16); "Arkansas supplied drug used in recent Oklahoma execution," Associated Press, November 8, 2010 (Appendix A, Tab 17); Rina Palta, "Inside the evolving market for lethal injection drugs," KALW Informant, November 9, 2010 (Appendix A, Tab 18); Nathan Koppel, "New Execution Drug Approved," Wall Street Journal, November 19, 2010 (Appendix A, Tab 19); Koppel, "The Sun Shines In Texas on Lethal Injection," Wall Street Journal, November 19, 2010 (Appendix A, Tab 20); Kathy Lohr, "Okla. considers using vet drug to execute inmate," NPR Morning Edition, November 19, 2010 (Appendix A, Tab 21); Mike Ward, "Texas has lethal drugs on hand to execute 39 condemned criminals," Austin American Statesman, November 19, 2010 (Appendix A, Tab 22); Kevin Horrigan, "Capital punishment: How will Missouri "lethally inject" if it runs out of a lethal drug?" St. Louis Today, November 21, 2010 (Appendix A, Tab 23); Sam Stanton and Denny Walsh, "Drug shortage stirs death penalty debate in the U.S. and beyond," Sacramento Bee, December 5, 2010 (Appendix A, Tab 24); "Oklahoma executes man using new drug combination," Associated Press, December 16, 2010 (Appendix A, Tab 25).

An execution in California scheduled for September 30, 2010, was delayed in part because the state's supply of sodium thiopental expired on October 1, and the state was unable to lawfully acquire a new supply of the controlled substance. The issue generated enormous media coverage in the state and nationally.

See Jesse McKinley and Malia Wollan, "Governor Postpones Execution in California," New York Times, September 27, 2010 (Appendix A, Tab 26); Michael Winter, "Drug shortage prompts Calif. to suspend executions after Sept. 30," USA Today, September 27, 2010 (Appendix A, Tab 27); Howard Mintz, "Execution drama unfolds in California," San Jose Mercury News, September 27, 2010 (Appendix A, Tab 28); Jesse McKinley and Malia Wollan, "Judges Cancels California Execution," New York Times, September 28, 2010 (Appendix A, Tab 29); CNN Wire Staff, "Court ruling may stall California execution," CNN, September 28, 2010 (Appendix A, Tab 30); Paul Elias, "Court orders hearing for condemned Calif. Inmate," Associated Press, September 28, 2010 (Appendix A, Tab 31); Carol Williams, "California's first execution in five years delayed by legal issues," Los Angeles Times, September 28, 2010 (Appendix A, Tab 32); Sam Stanton, "Death penalty reprieve ordered," Sacramento Bee, September 28, 2010 (Appendix A, Tab 33); Bob Egelko, "Court sends execution case back to U.S. judge," San Francisco Chronicle, September 28, 2010 (Appendix A, Tab 34); Julia Cheever, "Appeals Court Orders Federal Judge To Reconsider Stay Of Execution Request For San Quentin Inmate," Bay City News, September 28, 2010 (Appendix A, Tab 35); Paul Elias, "Fed judge blocks Calif. execution set for Thursday," Associated Press, September 29, 2010 (Appendix A, Tab 36); Paul Elias, "Calif execution try collapses after court setbacks," Associated Press, September 29, 2010 (Appendix A, Tab 37); Howard Mintz, "With time running out, judge blocks execution," San Jose Mercury News, September 29, 2010 (Appendix A, Tab 38); Kevin Fagan, "Execution: Expiration date near for death drug," San Francisco Chronicle, September 29, 2010 (Appendix A, Tab 39); Denny Walsh, "Federal judge halts scheduled Thursday execution," Sacramento Bee, September 29, 2010 (Appendix A, Tab 40); Carol Williams, "Judge halts execution of rapist-murderer," Los Angeles Times, September 29, 2010 (Appendix A, Tab 41); Vauhini Vara and Nathan Koppel, "Spotlight on Injection Drug as Judge Stays Execution," Wall Street journal, September 30, 2010 (Appendix A, Tab 42); Jack Leonard and Victoria Kim, "California Supreme Court ends legal battle over execution," Los Angeles Times, September 30, 2010 (Appendix A, Tab 43); Denny Walsh and Sam Stanton, "State drops effort to execute rapist-murderer by today," Sacramento Bee, September 30, 2010 (Appendix A, Tab 44); Howard Mintz, "No Executions in '10," San Jose Mercury News, September 30, 2010 (Appendix A, Tab 45); Julia Cheever, "Supreme Court Blocks Execution Of San Quentin Man, Schwarzenegger Decries Decision," Bay City News, September 30, 2010 (Appendix A, Tab 46).

At the end of September, the state of Arizona suddenly acquired a new supply of sodium thiopental. The state eventually revealed that it had imported the sodium thiopental from the United Kingdom, but did not explain how it had imported the drug despite the fact that federal law prohibits importation of controlled substances from sources that are not approved by the FDA. The origin and legality of the Arizona drug became the focus of an intense legal battle with extensive local, national and international media coverage.

See "Arizona says it may get drug needed for execution," Associated Press, September 23, 2010 (Appendix A, Tab 47); Michael Kiefer, "Arizona Supreme Court puts execution on hold," Arizona Republic, September 24, 2010 (Appendix A, Tab 48); Michael Kiefer, "Arizona death row inmate's lawyers want drug info from state," Arizona

Republic, October 15, 2010 (Appendix A, Tab 49); James Clark, "Some Call it Murder: Breaking the Law in the Name of Capital Punishment," Change.org, October 15, 2010 (Appendix A, Tab 50); Paul Davenport, "Arizona execution caught in drug supply debate," October 19, 2010 (Appendix A, Tab 51); Michael Kiefer, "Judge asks Arizona for execution-drug source," Arizona Republic, October 21, 2010 (Appendix A, Tab 52); "Ariz. inmate files suit challenging execution drug," Associated Press, October 21, 2010 (Appendix A, Tab 53); John Schwartz, "Use of Drug Challenged in Death Penalty Case," New York Times, October 23, 2010 (Appendix A, Tab 54); Michael Kiefer, "Arizona told to reveal source of drug for execution," Arizona Republic, October 23, 2010 (Appendix A, Tab 55); John Schwartz, "Arizona: Drug Question Holds Up Execution," New York Times, October 25, 2010 (Appendix A, Tab 56); Paul Davenport, "Judge blocks Arizona execution, state appeals," Associated Press, October, 25, 2010 (Appendix A, Tab 57); "Inmate's lawyers ask judge to discuss drug info," Associated Press, October 25, 2010 (Appendix A, Tab 58); "State ordered to reveal info about drug for execution use," Associated Press, October 25, 2010 (Appendix A, Tab 59); "Arizona submits info on execution drugs to judge," Associated Press, October 25, 2010 (Appendix A, Tab 60); "Judge puts off Arizona execution, saying state not forthcoming," CNN, October 25, 2010 (Appendix A, Tab 61); Michael Kiefer, "Judge to question whether Arizona illegally obtained lethal-injection drug," Arizona Republic, October 25, 2010 (Appendix A, Tab 62); "Brewer Denies Delay In Landrigan Execution," KPHO-TV, October 25, 2010 (Appendix A, Tab 63); James Clark, "Sudden Secrecy Surrounds Death Penalty Drugs," Change.org, October 25, 2010 (Appendix A, Tab 64); Michael Kiefer, "Judge delays execution set for today," Arizona Republic, October 26, 2010 (Appendix A, Tab 65); "US execution blocked in row over lethal drug source," Agence France-Presse, October 26, 2010 (Appendix A, Tab 66); George Miller, "Inmate delays execution through drug-source protest," Fierce Pharma Manufacturing, October 26, 2010 (Appendix A, Tab 67); John Schwartz, "Murderer executed in Arizona," New York Times, October 27, 2010 (Appendix A, Tab 68); Nina Totenberg, "Supreme Court OKs Foreign Lethal Injection Drug," NPR, October 27, 2010 (Appendix A, Tab 69); "State Goes Overseas For Lethal Injection Drug," Associated Press, October 27, 2010 (Appendix A, Tab 70); "Arizona convicted killer's last words: 'Boomer Sooner,'" CNN, October 27, 2010 (Appendix A, Tab 71); Michael Kiefer, "Arizona executes inmate after federal judge lifts stay," Arizona Republic, October 27, 2010 (Appendix A, Tab 72); "Arizona executes man after Supreme Court green light," Agence France-Presse, October 27, 2010 (Appendix A, Tab 73); David Savage, "Justice Elena Kagan's first vote is against an execution," Los Angeles Times, October 27, 2010 (Appendix A, Tab 74); Victoria Ward, "Arizona execute man with drug supplied by British company," Telegraph, October 27, 2010 (Appendix A, Tab 75); Chris McGreal, "Arizona execution goes ahead after stay lifted," Guardian, October 27, 2010 (Appendix A, Tab 76); Rina Palta, "What the Arizona execution means for the death penalty nationwide," KALW Informant, October 27, 2010 (Appendix A, Tab 77); Tony Mauro, "High Court Split Paves Way for Arizona Execution," National Law Journal, October 28, 2010 (Appendix A, Tab 78); Joan Biskupic and Kevin Johnson, "Justices not convinced by arguments to delay execution," USA Today, October 28, 2010 (Appendix A, Tab 79); George Miller, "Report: Archimedes anesthetic used in Arizona execution," Fierce Pharma Manufacturing, October 28, 2010 (Appendix A, Tab 80).

Although Arizona was able to carry out one execution using the controlled substance imported from the United Kingdom, the action was criticized and continues to raise serious legal questions. The Arizona Supreme Court subsequently delayed an execution due to questions about the origin and efficacy of the drug.

> *See* Dahlia Lithwick, "Lethal Deflection," Slate.com, October 28, 2010 (Appendix A, Tab 81); New York Times Editorial, "No Justification," October 29, 2010 (Appendix A, Tab 82); James Clark, "Jeffrey Landrigan Executed by Arizona Amid Continued Secrecy," Change.org, October 30, 2010 (Appendix A, Tab 83); "Lawyer files complaint over British execution drug," Agence France-Presse, November 19, 2010 (Appendix A, Tab 84); Michael Kiefer, "Arizona Supreme Court puts off date for execution," Arizona Republic, December 1, 2010 (Appendix A, Tab 85).

On October 6, 2010, the California Department of Corrections and Rehabilitation disclosed that it too had recently obtained 12 grams of sodium thiopental, with an expiration date of 2014, despite the nationwide shortage. The CDCR did not disclose the source of the drug or explain how it came into possession of the scare substance. Because the last supply of sodium thiopental produced by Hospira has an expiration date of 2011, the sodium thiopental in the CDCR's possession could not have been manufactured domestically.

> *See* Carol Williams, "State has enough sodium thiopental to execute four," Los Angeles Times, November 8, 2010 (Appendix A, Tab 86); "Drug issue stalls executions in California," UPI, November 8, 2010 (Appendix A, Tab 87); Julie Small, "Corrections chief promises to divulge how California secured lethal injection drug," KPCC, November 19, 2010 (Appendix A, Tab 88); James Clark, "State refuses to give up lethal drug dealer," Change.org, November 22, 2010 (Appendix A, Tab 89).

The ACLU-NC filed a request under the California Public Records Act (PRA) to get records regarding the CDCR's acquisition of sodium thiopental. The *Guardian,* the Village Voice and the Associated Press also filed PRA requests seeking the records. Because the CDCR failed to respond to any of these requests, the ACLU-NC subsequently filed suit to enforce the PRA request, resulting in a court order that forced the CDCR to disclose the records.

> *See* Rina Palta, "ACLU: Where did California get its execution drugs?" KALW Informant, November 18, 2010 (Appendix A, Tab 90); Ryan Gabrielson, "ACLU sues state over lethal injection drug," California Watch, November 19, 2010 (Appendix A, Tab 91); Carol Williams, "State ordered to reveal source of its lethal-injection drug," Los Angeles Times, December 2, 2010 (Appendix A, Tab 92); Julie Small, "California prison officials ordered to disclose information on lethal injection drug," KPCC, December 2, 2010 (Appendix A, Tab 93); Rina Palta, "Judge: California must make execution drug records public," KALW Informant, December 2, 2010 (Appendix A, Tab 94).

The day before releasing the records to the ACLU-NC, the CDCR disclosed to selected journalists that it had ordered 521 grams of sodium thiopental manufactured by a company in the

United Kingdom and that the state paid more than $36,000 to acquire the drug. The CDCR told the journalists that the controlled substance had arrived in the United States but was currently in the procession of the FDA awaiting inspection.

> *See* Paul Elias, "Calif gets supply of drug used during executions," Associated Press, December 6, 2010 (Appendix A, Tab 95); Rina Palta, "Where California got its execution drugs," KALW Informant, December 6, 2010 (Appendix A, Tab 96); Paul Elias, "San Quentin gets supply of drug used during executions," Associated Press, December 7, 2010 (Appendix A, Tab 97); Sam Stanton, "Execution drug came from UK, CA officials say," Sacramento Bee, December 7, 2010 (Appendix A, Tab 98); Carol Williams, "California now has enough drugs to execute 175 death row inmates," Los Angeles Times, December 7, 2010 (Appendix A, Tab 99); "California buys execution drug from Britain," Agence France-Presse, December 7, 2010 (Appendix A, Tab 100); Rula Al-Nasrawi, "Secrets of the state's death-drug deal," San Francisco Bay Guardian, December 7, 2010 (Appendix A, Tab 101); Julie Small, "Prisons release details of lethal injection drug acquisition," KPCC-FM, December 8, 2010 (Appendix A, Tab 102); James Clark, "California reveals its drug dealer," Change.org, December 8, 2010 (Appendix A, Tab 103); "California Bought Scarce Lethal-Injection Drug From British Firm," Crime Report, December 8, 2010 (Appendix A, Tab 104); "CA Waiting For Lethal Injection Drug Approval," Corrections.com, December 8, 2010 (Appendix A, Tab 105).

The CDCR produced 980 pages of records regarding the acquisition of execution drugs to the ACLU-NC on December 8, 2010. The ACLU-NC posted the documents to its website the same day. Since posting, the page has been visited 2,213 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website. The records are available at:

> http://www.aclunc.org/issues/criminal_justice/death_penalty/cdcr's_december_8,_2010_response_to_aclu_public_records_act_request.shtml.

The records disclosed by the CDCR raise serious questions about the conduct of state and federal government officials, and raise concern that state and federal laws were violated by the states' recent acquisition of sodium thiopental and by exchanges of controlled substances between different states. The information revealed in the records generated widespread media coverage in California, nationally and internationally.

> *See* Julie Small, "California's Corrections Department swapped lethal drugs with Arizona," KPCC, December 8, 2010 (Appendix A, Tab 106); George Miller, "Fierce Pharma Mfg - Imported death penalty drug to be tested by FDA," Fierce Pharma Manufacturing, December 8, 2010 (Appendix A, Tab 107); Paul Elias, "Docs show Calif.'s worldwide execution drug search," Associated Press, December 9, 2010 (Appendix A, Tab 108); Paul Elias, "Calif. scrambled for execution drug," Associated Press, December 9, 2010 (Appendix A, Tab 109); Rina Palta, "Timeline: California's scramble for execution drugs," KALW Informant, December 9, 2010 (Appendix A, Tab 110); Natasha Minsker, "I've got a secret mission for you," ACLU Blog of Rights,

December 9, 2010 (Appendix A, Tab 111); Jeff Neumann, "Arizona prison officials called 'life savers' for sharing lethal drug," Gawker.com, December 9, 2010 (Appendix A, Tab 112); Mike Ward, "California: Texas officials turned down request for execution drug," Statesman.com, December 9, 2010 (Appendix A, Tab 113); David Usborne, "Emails reveal gallows humour on death row," Independent, December 10, 2010 (Appendix A, Tab 114); Christopher Brauchli, "The executioner's drugs," Counter Punch, December 10, 2010 (Appendix A, Tab 115); Anthony Lydgate, Weekly Review, Harper's Magazine, December 14, 2010 (Appendix A, Tab 116); "Mysteries of the death-drug scramble," *San Francisco Bay Guardian*, December 14, 2010 (Appendix A, Tab 117); Ryan Gabrielson, "State withholds name of lethal drug supplier," California Watch, December 17, 2010 (Appendix A, Tab 118).

See also The Colbert Report, Tiny Triumphs—Lethal Drug Shortage, available at: http://www.colbertnation.com/the-colbert-report-videos/368731/december-15-2010/tiny-triumphs---lethal-drug-shortage?xrs=share_copy

In addition, the fact that state officials have been importing sodium thiopental from the United Kingdom has generated significant public outcry, legal challenges, and media attention, both in the United Kingdom, and in the United States. Following disclosure that states in the U.S. were acquiring execution drugs from sources in the UK, the government of the United Kingdom imposed new restrictions preventing the export of sodium thiopental for purposes of execution.

See Clive Stafford Smith, "The British company making a business out of killing," Guardian, October 26, 2010 (Appendix A, Tab 119); Owen Bowcott and Chris McGreal, "British firm denies exporting drug for Arizona execution," Guardian, October 27, 2010 (Appendix A, Tab 120); Robert Verkaik, "British company link to drug used in execution," Independent, October 27, 2010 (Appendix A, Tab 121); Michael Seamark, "British company denies exporting drug used in US execution after Arizona's supplies run dry," Daily Mail, October 28, 2010 (Appendix A, Tab 122); Ian Dunt, "Cable under fire for allowing execution drug sale," Politics.com, November 2, 2010 (Appendix A, Tab 123); David Cronin, "Not Executing, Just Enabling, IPS News, November 4, 2010 (Appendix A, Tab 124); Paddy, McGuffin, "Cable in court over death drug export," UK Morning Star, November 17, 2010 (Appendix A, Tab 125); "Cable attacked on 'execution drug.'" UK Press Associated, November 17, 2010 (Appendix A, Tab 126); John Aston, "Bid to ban export of 'execution' drug," Independent, November 17, 2010 (Appendix A, Tab 127); Benjamin Timmins, "British imposes controls on lethal injection drug," Associated Press, November 29, 2010 (Appendix A, Tab 128); Clive Stafford Smith, "A welcome U-turn from Vince Cable on execution drug," Guardian, November 29, 2010 (Appendix A, Tab 129); Michael Kiefer, "Controls imposed on lethal injection drug Arizona uses," Arizona Republic, November 29, 2010 (Appendix A, Tab 130); Dominic Casciani, "US lethal injection drug faces UK export restrictions," BBC, November 29, 2010 (Appendix A, Tab 131); Peter Walker, "Vince Cable restricts export of drug used in US executions," Guardian, November 29, 2010 (Appendix A, Tab 132); Daily Mail Reporter, "Human rights victory as Vince Cable imposes restrictions," November 29, 2010 (Appendix A, Tab 133); Tim Edwards, "Cable restricts export of lethal injection drug to US," First Post, November 29, 2010 (Appendix A, Tab 134);

Nathan Koppel and Jeanne Whalen, "U.K. Limits Execution Drug's Export," Wall Street Journal, November 30, 2010 (Appendix A, Tab 135); "U.K. to limit export of execution drug widely used in U.S.," MSNBC, November 30, 2010 (Appendix A, Tab 136); James Clark, "America's death penalty looses and ally," Change.org, November 30, 2010 (Appendix A, Tab 137); Mark Townsend, "US execution drugs supplied secretly by British companies," Guardian, December 19, 2010 (Appendix A, Tab 138); Paddy McGuffin, "Lethal drugs secretly shipped to California," UK Morning Star, December 19, 2010 (Appendix A, Tab 139).

As the forgoing demonstrates, questions about how state officials are acquiring controlled substances to use in executions and the role of federal officials in that process have generated exceptional, widespread media coverage in the United States and across the globe. The issue raises substantial questions about the integrity of government, at the state and federal level. The public has an urgent need for additional information as state officials continue to pursue new acquisitions of controlled substances for executions and seek to use substances in their possession of questionable origin and efficacy. The particular value of this information to the public will be lost if not obtained and disseminated quickly. For these reasons, the FDA should grant expedited processing of this FOIA request.

III. "Public Interest" Fee Waiver Request

We request a waiver of document search, review, and duplication fees on the grounds that disclosure of the requested records is in the public interest because disclosure is "likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." *See* 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. 20.46(a); see also 28 C.F.R. § 16.11(k)(1).

The FDA regulations further specify that the FDA will consider the following factors when determining if disclosure is in the public interest:

> (1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;
>
> (2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;
>
> (3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

> (4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

All of these factors are met here. First, the records sought pertain to the role of the FDA and other government officials in facilitating the acquisition by state officials of controlled substances for the purpose of execution. Second, disclosure of the records would reveal significant information that is currently unknown, specifically the details of how state officials acquired non-FDA approved controlled substances from outside the United States. Third, disclosure will assist the public generally in understanding a critical aspect of the capital punishment process in the United States and the requesters are in a position to disseminate the information broadly, as detailed below. Fourth, contributing to the public's understanding of the capital punishment process is a substantial and weighty public interest.

The requestors plan to disseminate widely to the public records disclosed as a result of this FOIA request. The ACLU-NC's communications department is a division of a nonprofit 501(c)(3) organization, and both the ACLU-NC's communications department and the *Guardian* are "representative[s] of the news media." They are well situated to disseminate information gained through this request to the public, to affected communities and to political and legal organizations. The requestors routinely obtain information about government activity (including through FOIA), analyze that information, and widely publish and disseminate that information to the press and to the public in a variety of ways including the following:

The ACLU-NC's communications department disseminates information through the website, http://www.aclunc.org, which had 477,995 page views in 2010. This website addresses civil liberties issues in depth and provides features on civil liberties issues on which the ACLU-NC is focused. As noted, the ACLU-NC posted the documents obtained from the CDCR regarding the acquisition of execution drugs on the day it received the records, December 8, 2010. Since posting, the page has been visited 2,835 times and viewed 2,835 times. From December 8, 2010 to December 13, 2010, it was the most frequently viewed page on the ACLU-NC website.

The ACLU-NC's communications department also publishes reporters, news briefings, right-to-know documents, and other materials that are disseminated to the public. Its material is widely available to everyone, including tax-exempt organizations, not-for-profit groups, law students and faculty, for no cost. ACLU-NC staff persons are frequent spokespersons in television and print media and make frequent public presentations at meetings and events. Finally, the ACLU-NC's communications department disseminates information through a newsletter, which is distributed to subscribers by mail. Due to these extensive publication activities, the ACLU-NC is a "representative of the news media" under the FOIA and agency regulations.

As noted, the *Guardian* is the largest circulation newsweekly in northern California, with audited weekly distribution of 100,000 copies. The paper covers breaking news, does detailed investigative reporting, publishes editorials and covers arts, entertainment, and lifestyle issues. The *Guardian* has received more than 100 state, local and national awards for journalistic

excellence. The *Guardian* is a member of the California Newspaper Publishers Association and the Association of Alternative Newsweeklies.

Finally, disclosure of the requested records is not in the requestors' commercial interest. See 21 C.F.R. § 20.46(c). The records requested are not sought for commercial use and the ACLU-NC plans to disseminate the information disclosed as a result of this FOIA request to the public at no cost. Thus, a fee waiver would fulfill Congress's legislative intent in amending FOIA. *See Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003) ("Congress amended FOIA to ensure that it be 'liberally construed in favor of waivers for noncommercial requesters.'") (citation omitted).

IV. News Media Status Fee Limitation Request

We also request a waiver of document search and reproduction fees on the grounds that the requestors qualify as "representatives of the news media" and the records are not sought for commercial use. 21 C.F.R. § 20.45(a)(2). The *Guardian* is a newsweekly. The ACLU-NC also meets the statutory and regulatory definitions of a "representative of the news media" because they are "entit[ies] that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." 5 U.S.C. § 552(a)(4)(A)(ii); *see also Nat'l Sec. Archive v. Dep't of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989) (finding that an organization that "gathers information from a variety of sources," exercises editorial discretion in selecting and organizing documents, "devises indices and finding aids," and "distributes the resulting work to the public" is a "representative of the news media" for purposes of the FOIA); *cf. ACLU v. Dep't of Justice*, 321 F. Supp. 2d at 30 n.5 (finding non-profit public interest group to be "primarily engaged in disseminating information").[5]

Notably, courts have found other organizations whose missions, functions, publishing, and public education activities are similar in kind to the ACLU's to be "representatives of the news media." *See, e.g., Elec. Privacy Info. Ctr. v. Dep't of Defense*, 241 F. Supp. 2d 5, 10-15 (D.D.C. 2003) (finding non-profit public interest group that disseminated an electronic newsletter and published books was a "representative of the media" for purposes of FOIA); *Nat'l Security Archive*, 880 F.2d at 1387; *Judicial Watch, Inc. v. Dep't of Justice*, 133 F. Supp. 2d 52, 53-54 (D.D.C. 2000) (finding Judicial Watch, self-described as a "public interest law firm," a news media requester).[6]

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[5] Fees associated with responding to FOIA requests are regularly waived for the ACLU, and a number of agencies have determined that the ACLU is a "representative of the news media" for the purposes of FOIA, including the Departments of Justice, State, and Commerce. In December 2008, the Department of Justice found that the ACLU was a "representative of the news media" for the purposes of FOIA in the context of a request for documents relating to the detention, interrogation, treatment, or prosecution of suspected terrorists.

[6] Courts have founds these organizations to be "representatives of the news media" even though they engage in litigation and lobbying activities beyond their dissemination of information/public education activities. *See, e.g., Elec. Privacy Info. Ctr.*, 241 F. Supp. 2d 5; *Nat'l Sec. Archive*, 880 F.2d at 1387; *see also Judicial Watch, Inc.*, 133 F. Supp. 2d at 53-54; *see also Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 260 (D.D.C. 2005) (finding Leadership Conference to be primarily engaged in disseminating information even though it engages in substantial amounts of legislative advocacy beyond its publication and public education functions).

* * *

If this request is denied in whole or in part, we ask that you justify all withholdings by reference to specific exemptions to the FOIA. We expect the release of all segregable portions of otherwise exempt material. If the fee waivers are denied, the requesters are prepared to pay fees up to $100, and request to be informed of further fees that may be charged, but reserve the right to appeal a denial of fee waivers.

Thank you for your prompt attention to this matter. Please furnish all applicable records to Natasha Minsker, American Civil Liberties Union of Northern California, 39 Drumm Street, San Francisco, California 94111, telephone (415) 621-2493, email nminsker@aclunc.org.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

Certification

Pursuant to 21 C.F.R. § 20.44(d), I, Natasha Minsker, certify that the information in this request is true and correct to the best of my knowledge and belief.

January 4, 2011

Signed in San Francisco, California

Natasha Minsker

Exh. B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Date: APR 1 1 2011

Request Number: 2011-2661

Natasha Minsker
ACLU
39 Drumm St
San Francisco, CA 94111

Subject of Request: Deletions to previously released records

Dear Sir/Madam:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA). I apologize for any delay in responding to you. The paragraphs checked below apply to your request:

[X] We have already provided records from the New Orleans District Office under FOIA 2011-319, and we are now restoring some of the material that was redacted from those records, and we are denying the remainder of the redactions.

[ ] We are denying your entire request.

[X] The following exemption(s) of FOIA, 5 U.S.C. 552, indicated by an "X" is/are the authority for denying you access to the non-disclosable material. We have enclosed copies of FOIA and regulations for your information.

[ ] (b)(1) National security information concerning the national defense or foreign policy
[ ] (b)(2) Internal rules and practices
[ ] (b)(3) Prohibited from disclosure by other laws
[X] (b)(4) Trade secret and confidential commercial information
[ ] (b)(5) Certain interagency and intra-agency communications
[ ] (b)(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy
[X] (b)(7) Records or information compiled for law enforcement purposes when disclosure
  [ ] (A) could reasonably be expected to interfere with enforcement proceedings
  [ ] (B) would deprive a person of a right to a fair trial or an impartial adjudication

[X] (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy
[ ] (D) could reasonably be expected to disclose the identity of a confidential source
[ ] (E) would disclose techniques, procedures or guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law
[ ] (F) could reasonably be expected to endanger the life or physical safety of an individual

[X] The following section(s) of the implementing regulations of the Department of Health and Human Services (DHHS) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

[ ] 5.63	[ ] 5.68(a)
[ ] 5.64	[ ] 5.68(b)
[X] 5.65	[X] 5.68(c)
[ ] 5.66	[ ] 5.68(d)
[ ] 5.67	[ ] 5.68(e)
	[ ] 5.68(f)
	[ ] Other:

[X] The following section(s) of the implementing regulations of FDA and reason(s) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 21.

[X] 20.61(c) Trade Secret and Confidential Commercial Information.

[X] 20.64(a)(3) and 514.11(e)(c)(3)(vi) Investigatory record(s) compiled for law enforcement purposes, the disclosure of which could reasonably be expected to constitute a clearly unwarranted invasion of the personal privacy of the complainant, in general. Also, records (such as adverse reaction reports, product experience reports, consumer complaints and other similar data and information) relating to a specific individual (named in your request) or specific incident (identified in your request), in particular. FDA will not release such record(s) unless the request is accompanied by the written consent of the person who submitted the report to FDA and the individual who is the subject of the report. The record(s) will be disclosed to the individual who is the subject of the report upon request.

[X] Other laws, in addition to FOIA, may prohibit disclosure of the information you requested. The following law(s) applicable to this denial is/are indicated by an "X".

[X] 18 U.S.C. 1905 [Federal Trade Secrets Act]
[X] 21 U.S.C. 331(j) [Federal Food, Drug, and Cosmetic Act]
[ ] 21 U.S.C. 360j(c) [Federal Food, Drug, and Cosmetic Act]
[ ] 5 U.S.C. 107(a)(2) Appendix 4 [Ethics in Government Act]

[X] The estimated volume of the records we are denying is: Remaining redactions to New Orleans records.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. You should file any such appeal within 30 days and address it to the Deputy Assistant Secretary for Public Affairs (Media), U.S. Department of Health and Human Services, 7700 Wisconsin Ave., Suite 920, Bethesda, MD 20857.

Sincerely yours,

Frederick J. Sadler
Director
Division of Freedom of Information

Enclosures, as indicated

Exh. C

ACLU
AMERICAN CIVIL LIBERTIES UNION of
GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

February 15, 2011

U.S. Food and Drug Administration
Division of Freedom of Information HFI-35
5600 Fishers Lane Room 6-30
Rockville, MD 20857

Re: FOIA Appeal, Reference # 2011-319

Dear FOIA Officer:

Requestors American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) write to request reconsideration of the Food and Drug Administration's (FDA) decision to withhold materials or information in the records released in response to FOIA Request # 2011-319 (the "Request").

The Request seeks records pertaining to the acquisition of controlled substances by state officials for the purpose of carrying out executions of condemned prisoners by lethal injection. *See* Exh. A (FOIA Request dated January 4, 2011). Requestors received two responses from Legal Administrative Specialist Timothy J. Trepagnier, dated January 19, 2011 and February 8, 2011. Exh. B (Response to FOIA Request from Timothy J. Trepagnier dated January 19, 2011), Exh. C (Response to FOIA Request from Timothy J. Trepagnier dated February 8, 2011). Mr. Trepagnier's January 19 letter was accompanied by 63 pages of redacted documents (the "January 19 release") and his February 8 letter was accompanied by 49 pages of redacted documents (the "February 8 release"), some of which overlapped with the January 19 release. Both letters responding to the Request stated that certain material was redacted from the records produced by the FDA because the FDA preliminarily determined that such information was not required to be publicly disclosed and disclosure was not appropriate. *See* Exhs. B, C.

We respectfully request reconsideration of this preliminary determination and the release of unredacted information responsive to the Request. Requestors also seek apparently withheld documents, as well as clarification as to if and/or when the FDA will search files beyond those contained in its New Orleans District Office.

Redactions Pursuant to 5 U.S.C. § 552(b)

ACLU-NC and the *Guardian* requested the release of twelve distinct categories of information pertaining to the importation, transfer, or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution. In response, the New Orleans District Office released

AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA
39 DRUMM STREET, SAN FRANCISCO, CA 94111 | T/415.621.2493 | F/415.255.1478 | TTY/415.863.7832 | WWW.ACLUNC.ORG

112 pages of heavily redacted material from the New Orleans District of the FDA, in two separate sets.[1] The FDA justifies the redactions by reference to four statutory exemptions:

- Exemption 4, 5 U.S.C. § 552(b)(4), which exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"

- Exemption 5, 5 U.S.C. § 552(b)(5), which exempts "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency,"

- Exemption 7(C), 5 U.S.C. § 552(b)(7)(C), which exempts "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information ... could reasonably be expected to constitute an unwarranted invasion of personal privacy," and

- Exemption 7(E), 5 U.S.C. § 552(b)(7)(E), which exempts law enforcement records or information, but only to the extent that production "would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law."

The FDA's inconsistent application of these exemptions, both within the releases as well as between the January 19 and February 8 releases, demonstrates that the FDA has incorrectly applied these exemptions and, as a result, is unlawfully withholding information the public has a right to receive. For example:

- The January 19 release includes an e-mail from Ruth Dixon to Domenic Veneziano, in which Ms. Dixon mentions that certain officials are "receiving significant pressure from the Governor's office." This e-mail appears in the February 8 release as well, but the part that mentions pressure from the Governor is redacted. *See* Exh. D (Comparison of Ruth Dixon e-mail dated December 9, 2010).

- In the January 19 release, all information that would identify the states that imported the drugs has been redacted. Those documents provided a second time in the February 8 release disclose this information. *See* Exh. E (Comparison of Susan Halpenny email dated December 20, 2010). Yet, because not all of the documents disclosed on January 19 were included in the February 8 release, much of the information about which states ordered the drugs still has not been released to the public.

- In a fax from the Arkansas Department of Correction, the redaction of quantity and price is marked (b)(4), which is an exemption for trade secrets or privileged financial information. *See* Exh. F (Fax from Arkansas Department of Correction dated September 10, 2010). But in a fax from the Georgia Department of Corrections, an essentially

[1] To date, the FDA has apparently not searched for responsive records beyond those in the New Orleans District's files, and has denied Requestors' request for expedited processing of their FOIA request. By separate letter dated February 1, 2011, Requestors have sought reconsideration of the denial of expedited processing.

identical redaction of quantity and price are marked (b)(7)(E), which exempts certain records that disclose techniques for law enforcement investigations or prosecutions. *See* Exh. G (Fax from Georgia Department of Corrections dated August 4, 2010).

Not only are these exemptions inapplicable, as discussed below, but the inconsistent redactions and inconsistent justifications for redaction show that the FDA is not consistently or accurately applying the exemptions to disclosure under FOIA, and that the agency does not have legal cause to withhold much of the information currently redacted from the documents.

Similarly, many of the redactions are so imprecise that they raise questions about whether the FDA is withholding critical information simply in error. Specifically, some blacklines result in redactions of surrounding text that plainly should not have been redacted. For example, an e-mail from David Thomas to Anthony Taube on September 27, 2010 appears several times, but depending on the font size of the printout, different portions of the text are blocked out. In one instance, the words immediately above and below a port of entry are deleted, but in other instances, smaller font and more precise blacklines reveal that the words "London" and "made" were improperly blocked out. *See* Exh. H (Comparison of David Thomas e-mail dated September 27, 2010). Several other instances of imprecise blacklining are scattered throughout the February 8 release, and it is likely that portions of records have been redacted unintentionally. *See, e.g.*, Exh. I (E-mail from David Thomas to Greta Budweg et al. dated September 27, 2010). Requestors seek full release of these improperly redacted materials.

Overall, the agency's redactions are excessive and unjustified. The quantity of drugs in each shipment has been redacted from all documents—FDA Notices of Action, Customs Entry forms, supplier invoices, and all other correspondence. Entire manifest reports and airbill entry forms have been blocked out, making it impossible to tell which agency, company, or state generated or received the document. *See, e.g.*, Exh. J (Manifest report dated June 28, 2010). Even if some of the redactions were proper under the referenced exemptions (which Requestors dispute), they are so numerous that they are far beyond any reasonable application of the exemptions. Furthermore, numerous redactions in the February 8 release are marked "NEC" which, as far as Requestors are aware, is not a category of permitted exemptions or any part of the Freedom of Information Act. To the extent the FDA has withheld information marked "NEC," we request that such information be disclosed or that the FDA provide an explanation for the withholding by reference to a statutory exemption under 5 U.S.C. § 552.

The redactions that do refer to statutory exemptions are also excessive. First, the liberal use of Exemption 5 is unwarranted. To qualify for protection under Exemption 5, a document must satisfy two conditions: "its source must be a Government agency, and it must fall within the ambit of a privilege against discovery under judicial standards that would govern litigation against the agency that holds it." *Department of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001). Requestors do not know the content or nature of all the (b)(5) redactions, but based on the examples we do have, it is unlikely that any of the redacted information qualifies under Exemption 5. Following are a sampling of improper applications of the exemption:

- In an e-mail from John Solomon of the South Carolina Department of Corrections, Mr. Solomon inquires whether a jurisdictional issue between the FDA and the DEA has been decided. He observes that if the question is not resolved soon, he "may be exchanging Christmas cards" with the FDA (January 19 release). This e-mail is also in the February 8 release, but both the reference to the jurisdictional problem and the remark about Christmas cards is redacted based on Exemption 5. *See* Exh. K (Comparison of John Solomon e-mail dated December 1, 2010). This redaction is improper: the question about

inter-agency jurisdiction does not reveal any privileged administrative deliberations, nor is the comment about exchanging holiday cards privileged.

- As noted above, the January 19 release includes an e-mail from Ruth Dixon to Domenic Veneziano, in which Ms. Dixon mentions that certain officials are "receiving significant pressure from the Governor's office." This comment has been redacted in the February 8 release, with Exemption 5 cited as the justification. *See* Exh. L (Comparison of Ruth Dixon e-mail dated December 9, 2010). This redaction is particularly disturbing because not only is there no privileged information in this sentence, it could also be construed as an attempt by the FDA to hide potential government misconduct, which goes against the primary purpose of the Freedom of Information Act.

- In another e-mail from Christopher Boulmay to John McAuliffe, part of a sentence is redacted under Exemption 7(E) in the January 19 release, but in the February 8 release, the entire sentence is redacted under Exemption 5. *See* Exh. M (Comparison of Christopher Boulmay e-mail dated November 30, 2010). Requestors dispute the applicability of either exemption, and the conflicting references to different exemptions suggests the FDA does not have a good reason for withholding the information.

These are just a few examples of the unjustified use of Exemption 5. For the reasons explained above, Requestors seek full disclosure of all materials withheld under the exemption.

Second, many of the redactions of price and quantity are marked as exempt under Exemption 4, but this exemption is inapplicable. The amount of money a state spends on lethal injection drugs is not privileged or confidential commercial or financial information or a trade secret. *See, e.g.*, *Racal-Milgo Government Systems, Inc. v. Small Business Administration*, 559 F. Supp. 4 (D.D.C. 1981) (ordering disclosure of unit prices charged to the government for computer equipment and finding Exemption 4 inapplicable). The price a state pays for sodium thiopental, for example, is neither "a secret, commercially valuable plan, formula, process, or device ... that can be said to be the end product of either innovation or substantial effort," *Public Citizen Health Research Group v. Food and Drug Administration*, 704 F.2d 1280, 1288 (D.C. Cir. 1983), nor is disclosure of such information likely to "impair the Government's ability to obtain necessary information in the future" or "cause substantial harm to the competitive position of the person from whom the information was obtained," *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). Moreover, the redacted prices are at least two to seven months old, as the most recent shipment has a recorded entry date of November 19, 2010. *See* Exh. N (Customs Entry form dated November 24, 2010). Historical prices are even less sensitive than current prices, and are very unlikely to impair the Government's ability to obtain information or goods in the future or cause competitive harm. Indeed, the California Department of Corrections and Rehabilitation (CDCR) has already disclosed records revealing that it paid $36,000 for one of the shipments covered by these FDA records.

Nor is the quantity of drugs purchased or imported exempt under Exemption 4: the public is entitled to be informed about how much drugs the government is buying to carry out executions and how much those drugs cost. This information is important because it allows citizens to decide whether the government is spending taxpayer money wisely. *See Racal-Milgo*, 559 F. Supp. at 6 ("Adequate information enables the public to evaluate the wisdom and efficiency of federal programs and expenditures."). The public has a right to know how and why a government agency decided to spend public funds as it did. *Martin Marietta Corp. v. Dalton*, 974 F. Supp. 37, 41 (D.D.C. 1997). *See also U.S. Department of Justice v. Reporters Committee for Freedom of Press*, 489 U.S. 749, 773 (1989) (basic purpose of the Freedom of Information Act "focuses on the citizens' right to be informed about what their

government is up to"). Again, the CDCR has already disclosed records showing that it purchased 521 grams of sodium thiopental from a source in the United Kingdom, in one of the shipments covered by these records.

In other price and quantity redactions, the FDA (inconsistently) makes reference to Exemption 7(E). Publication of the price and quantity of a lethal injection drug would not reveal any "techniques and procedures for law enforcement investigations or prosecutions," let alone create a reasonable expectation of risk of "circumvention of the law." As explained multiple times in the records, states are seeking to import the drugs to carry out death sentences—at this point, any investigation or prosecution should have long been concluded. Nor does disclosure provide any information that would help a person circumvent the law. Price and quantity numbers do not reveal any information about how an execution is carried out –the manner of execution and drugs used by each state is already public information. Thus, no techniques or procedures are compromised by disclosing information about price and quantity of drugs imported from abroad.

The FDA's reliance on Exemption 7(C) is also overbroad. In the January 19 release, Exemption 7(C) is used to prevent identification of state officials and even state names. Although the February 8 release discloses much of this information, Requestors do not know whether all of the information about the states that purchased or imported controlled substances has been identified because not all of the records contained in the January 19 release were included in the February 8 release. We request that all such information be released, as Exemption 7(C) does not apply here as the FDA belatedly realized.

Exemption 7(C) does not apply to this information because it is not an unwarranted invasion of *personal* privacy to reveal which *states* are purchasing, importing, or receiving controlled substances for the purpose of execution. Nor should the names of state officers be withheld, as "a government employee's privacy interests may be diminished to the extent it might disclose official misconduct." *Lissner v. U.S. Customs Service*, 241 F.3d 1220, 1223 (9th Cir. 2001). However, potential government misconduct is not required for disclosure of individual names: "Exemption 7(C) does not apply to information relating to business judgments and relationships when the information does not implicate any business actor in a crime.... An agency may not exempt from disclosure all of the materials in an investigatory record solely on the grounds that the record includes some information which identifies a private citizen or provides that person's name and address." *Center to Prevent Handgun Violence v. U.S. Department of Treasury*, 981 F. Supp. 20, 23-24 (D.D.C. 1997) (ordering release of names and locations of federal firearms licensees).

The FDA's own inconsistent application of 7(C) is telling. In the February 8 release, a letter from the General Counsel of California to the FDA mentions a state official (John McAuliffe), whose name is redacted based on Exemption 7(C). The same letter is also included in the January 19 release, but there, Mr. McAuliffe's name is not redacted. Elsewhere in the February 8 release, Mr. McAuliffe's name is left unredacted. This uneven disclosure is just one example of unnecessary redaction. We seek full release of any other information that has been unjustifiably withheld.

Even if the names of some individual state officers may be legitimately withheld in some documents, it is not reasonable to characterize disclosure of the identity of the *state* as an unwarranted invasion of personal privacy. To the extent the responsive records reveal the names of states, cities, government addresses, or government e-mail domain names, or refer to government officials' titles, Requestors dispute the FDA's decision to redact such information. This information falls outside the exemptions of Exemption 7(C) and therefore must be disclosed. At the very minimum, the FDA should

disclose the names of the states making each purchase, the area code for all phone numbers contained in the records, and the domain names for all email addresses.

Further, although Requestors cannot know all the types of information that have been redacted or withheld from the released records, we believe a large portion, if not all, of the redacted information is required to be publicly disclosed. The referenced exemptions under § 552(b) are inapplicable to much of the information that has been withheld. Requestors therefore seek reconsideration of the decision to redact any information, including as to the identities of the state or local governments that imported, transferred, or purchased the controlled substances, the quantities acquired, and the amounts paid, as well as any other information responsive to the Request.

Unreleased Records

The released documents appear to cover five shipments of controlled substances. The records for four of the shipments, released August 13, 2010 (Entry Number 112-7818637-8), September 28, 2010 (Entry Number 112-8992979-0), and January 6, 2010 (Entry Numbers 112-9673446-4 and 112-9938358-2), include "Notice of FDA Action" forms. However, records for Entry Number 112-9247186-3, which arrived on October 6, 2010, include a form from the U.S. Customs Service but no Notice of FDA Action. Was the Notice of FDA Action overlooked in the records search or was it intentionally withheld? Requestors seek production of this Notice. If the Notice was intentionally withheld, Requestors are entitled to know the reason(s) for the withholding.

Furthermore, the product description for the Entry Number 112-8992979-0 released on September 28, 2010 lists only Thiopental Sodium, but the e-mail correspondence related to this entry refers to "3 components of a lethal injection, 1) Thiopental, 2) Pancuronium, 3) Potassium Chloride." Were there additional entry forms or records for the pancuronium or potassium chloride? If so, Requestors seek production of these documents or the reason(s) for the withholding.

The same e-mail correspondence also makes reference to "UPS-9066861-5," appears to be another shipment. *See* Exh. O (E-mail from Greta Budweg dated September 27, 2010). Are there unreleased records related to this shipment, or any other shipments? If so, Requestors seek production of these documents or the reason(s) for the withholding.

Responses from Other Districts

All of the released records originated from the New Orleans District, and the letters accompanying the release described the documents as the result of a "search of the New Orleans District files," not of all the FDA files pertaining to the Request. *See* Exhs. B, C. Although the letters from Mr. Trepagnier states that Requestors "may hear from other FDA offices," we have received no indication whether other FDA district files will be searched or whether we will receive additional records from other districts, nor was there any explanation why other districts might not be searched. Without this information, we cannot know whether we need to object to additionally withheld materials. For this reason, we request that the FDA indicate which, if any, other district files will be searched and released.

* * *

For the foregoing reasons, we respectfully request that you reconsider the preliminary determination that the requested information is not required to be publicly disclosed and that the FDA confirm when offices other than the New Orleans District Office will be searched for responsive records. We look forward to your prompt response.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Also on behalf of Tim Redmond
Executive Editor, *San Francisco Bay Guardian*

Exh. D

#2 Martin Luther King, Jr. Drive
East Tower, Room 754
Atlanta, GA 30334
Fax (404) 657-4399
Voice (404) 656-5999

Georgia Department of Corrections Purchasing

Faxed 8/10/10 @ 2:28 p.m. JR

Fax

To: (b) (6) From: C. SMITH

Fax: 701.333.3577 Pages: 3 (INCLUDING COVER PAGE)

Phone: Date:

Re: TRACKING #6881604174247 CC:
ENTRY # 112-7418637-8

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

#2 Martin Luther King, Jr. Drive
East Tower, Room 754
Atlanta, GA 30334
Fax (404) 657-4399
Voice (404) 656-5999

Georgia Department of Corrections Purchasing

Faxed 8/10/10 2:29 P.M. JR

Fax

To: (b) (7)(C) From: C. SMITH

Fax: 701 (b) (7)(C) Pages: 3 (INCLUDING COVER PAGE)

Phone: Date:

Re: TRACKING # (b) (4) ENTRY # 112-7918637-8 CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Exh E

From: Boulmay, Christopher
Sent: Tuesday, November 30, 2010 4:00 PM
To: 'McAuliffe, John@CDCR'
Cc: Kernan, Scott@CDCR; Halpenny, Susan M; Dixon, Ruth P
Subject: RE: FDA entry item # 112-99-38358-2
John,

This entry is currently under review by our DIOP branch. (b)(6) If you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

Christopher Boulmay
Consumer Safety Officer
US Food & Drug Administration
NOL-DO: Memphis R.P.
Phone: (901) 333-3528
Fax: (901) 333-3577

From: McAuliffe, John@CDCR [mailto:John.McAuliffe@cdcr.ca.gov]
Sent: Tuesday, November 30, 2010 3:37 PM
To: Boulmay, Christopher
Cc: Kernan, Scott@CDCR
Subject: FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to Chemique Pharmaceuticals, Inc. 13306 East Whittier Boulevard, Whittier, CA. 90602-3200 by FED-EX. (Barbara Taffy is the FED-EX contact person) I also called your phone number 901-333-3528 and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

John McAuliffe
California Department of Corrections and Rehabilitation

From: Boulmay, Christopher
Sent: Tuesday, November 30, 2010 4:00 PM
To: 'McAuliffe, John@CDCR'
Cc: Kernan, Scott@CDCR; Halpenny, Susan M; Dixon, Ruth P
Subject: RE: FDA entry item # 112-99-38358-2
John,

This entry is currently under review by our DIOP branch. (b) (5) [redacted]. If you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

Christopher Boulmay
Consumer Safety Officer
US Food & Drug Administration
NOL-DO: Memphis R.P.
Phone: (901) 333-3528
Fax: (901) 333-3577

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Sent: Tuesday, November 30, 2010 3:37 PM
To: Boulmay, Christopher
Cc: Kernan, Scott@CDCR
Subject: FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to Chemique Pharmaceuticals, Inc. 13306 East Whittier Boulevard, Whittier, CA. 90602-3200 by FED-EX. (b) (6) is the FED-EX contact person) I also called your phone number 901-333-3528 and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

John McAuliffe
California Department of Corrections and Rehabilitation

Exh. E

Dream Pharma Ltd.

176 Horn Lane, Acton, London. W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: 2727INV

Date: 19-11-2010

Address:
(b) (4)

Tel: (b) (4)

VAT no:
Purchase Order:

Delivery Address:
(b) (4)

(b) (4)

Currency: USD - US Dollar
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW6022 EXP: 05/14	(b) (4)		

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): (b) (4)	VAT (World Zero): (b) (4)
Delivery: (b) (4)	Previous Balance: (b) (4)
Insurance: (b) (4)	Total: (b) (4) USD - US Dollar
	Payment Method: Prepayment Thank You

Shipping Details

Packing: (b) (4)	Gross Weight (Kg) (b) (4) Net Weight (Kg): (b) (4)
Tariff: (b) (4)	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd

DREAM PHARMA LTD
176 Horn Lane
Acton, London W3 6PJ
Tel: 020-8992-7000
Fax: 020-8992-7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: (b) (4) VAT No. (b) (4)
Director: M. Alavi

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: 2668INV
Date: 17-09-2010

Address:
Arkansas Department of Correction
Central Administration Office
6814 Princeton Pike
Pine Bluff, AR 71602-9411
Fedex: 4512-1458-6
Tel: 870-550 - 7307

VAT no:
Purchase Order:

Delivery Address:
Arkansas Department of Correction
Att: Wendy Kelley, Deputy Director
Central Administration Office
6814 Princeton Pike
Pine Bluff, AR 71602-9411
Fedex: 4512-1458-6
870-550 - 7307
Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW6022 EXP: 05/14	(b) (4)		590.25

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): (b) (4)	VAT (World Zero) (b) (4)
Delivery (b) (4)	Previous Balance: (b) (4)
Insurance: (b) (4)	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: one box	Gross Weight (Kg): (b) (4) Net Weight (Kg):
Tariff: (b) (4)	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi - Dream Pharma Ltd 176 Horn Lane Acton London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

PHARMA LTD

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: (b) (4) VAT No: (b) (4)
Director: M. Alavi

Exh G

STATE OF CALIFORNIA —DEPARTMENT OF CORRECTIONS AND REHABILITATION ARNOLD SCHWARZENEGGER, GOVERNOR

OFFICE OF THE SECRETARY
P.O. Box 942883
Sacramento, CA 94283-0001

December 9, 2010

Ms. Ruth Dixon
Department of Health and Human Services
Food and Drug Administration

Dear Ms. Dixon:

Since 1993, California law has authorized capital punishment by lethal injection pursuant to Penal Code Section 3604. The law states the punishment of death shall be inflicted by the administration of an intravenous injection of substances in a lethal quantity sufficient to cause death. On May 1, 2009, the California Department of Corrections and Rehabilitation (CDCR) promulgated regulations setting forth the requirements for administering capital punishment by lethal injection pursuant to Administrative Procedure Act. Those regulations became effective on August 29, 2010. The regulations provide for the use of three chemicals; sodium thiopental, pancuronium bromide, and potassium chloride.

There is a national shortage of sodium thiopental. California, like many other states, has been actively seeking supplies of the sodium thiopental for future executions. California's supply of sodium thiopental expired on October 1, 2010. On November 22, 2010, CDCR notified the United States District Court for the Northern District of California that it had ordered 521 grams of sodium thiopental that expires in 2014 from a manufacturer based in England (FDA # 112-99-38358-2). CDCR expected to receive the sodium thiopental during the week of November 29, 2010. Although CDCR followed all proper procedures and the Drug Enforcement Agency and United States Customs has approved the shipment, this shipment is currently be held by your office.

Per your conversation with John McAuliffe, we are asking for the immediate release and shipment of the 521 grams of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or Mr. McAuliffe at (707) 480-6766.

Sincerely,

BENJAMIN T. RICE
General Counsel

cc: John McAuliffe

STATE OF CALIFORNIA—DEPARTMENT OF CORRECTIONS AND REHABILITATION ARNOLD SCHWARZENEGGER, GOVERNOR

OFFICE OF THE SECRETARY
P.O. Box 942883
Sacramento, CA 94283-0001

December 9, 2010

Ms. Ruth Dixon
Department of Health and Human Services
Food and Drug Administration

Dear Ms. Dixon:

Since 1993, California law has authorized capital punishment by lethal injection pursuant to Penal Code Section 3604. The law states the punishment of death shall be inflicted by the administration of an intravenous injection of substances in a lethal quantity sufficient to cause death. On May 1, 2009, the California Department of Corrections and Rehabilitation (CDCR) promulgated regulations setting forth the requirements for administering capital punishment by lethal injection pursuant to Administrative Procedure Act. Those regulations became effective on August 29, 2010. The regulations provide for the use of three chemicals; sodium thiopental, pancuronium bromide, and potassium chloride.

There is a national shortage of sodium thiopental. California, like many other states, has been actively seeking supplies of the sodium thiopental for future executions. California's supply of sodium thiopental expired on October 1, 2010. On November 22, 2010, CDCR notified the United States District Court for the Northern District of California that it had ordered [redacted] grams of sodium thiopental that expires in 2014 from a manufacturer based in England (FDA # 112-99-38358-2). CDCR expected to receive the sodium thiopental during the week of November 29, 2010. Although CDCR followed all proper procedures and the Drug Enforcement Agency and United States Customs has approved the shipment, this shipment is currently be held by your office.

Per your conversation with John McAuliffe, we are asking for the immediate release and shipment of the [redacted] grams of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or Mr. McAuliffe at (707) 480-6766.

Sincerely,

BENJAMIN T. RICE
General Counsel

cc: John McAuliffe

Exh. I

Dohm, Julie

From: Bowen, Patrick A
Sent: Wednesday, October 27, 2010 3:22 PM
To: ORA HQ DIOP IPM; ORA HQ DIOP Employees
Cc: ORA RFDDs; ORA DIBs; ORA DCBs; ORA DDs; ORA Lab Directors; Elder, David K.; Batista, Huascar R
Subject: IMPORT BULLETIN #60-B08

Date: 10/27/2010

From: DIRECTOR, DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: IMPORT BULLETIN #60-B08, "SHORTAGE OF SODIUM PENTATHOL AKA SODIUM THIOPENTAL"

TO: IMPORT PROGRAM MANAGERS

* * * * * IMPORT BULLETIN * * * * *

NOTE: THIS IS A PRIVILEGED INTERNAL FDA DOCUMENT AND NOT INTENDED FOR RELEASE TO THE PUBLIC.

BACKGROUND: Sodium Pentathol is not being produced in the United States and is currently unavailable. It is not scheduled to be available until the first quarter of 2011.

GUIDANCE: Districts receiving shipments of Sodium Pentathol or Sodium Thiopental are asked to contact CDR Domenic Veneziano, Director of FDA's Division of Import Operations and Policy at (240)888-9316 for further instructions.

Appropriate OASIS screening criteria has been set.

MANUFACTURER:	ALL
COUNTRY:	ALL
PRODUCT(S):	Sodium Pentathol Sodium Thiopental
PRODUCT CODES:	60Q[][]28
PAF:	(AAP) Approvals (REG) Registrations & Listing
PAC:	56008H
EXPIRATION DATE:	90 days from date of issuance
RECOMMENDED BY:	DIOP, HFC-170
FOI:	No purging required
KEY WORDS:	Anesthetic, sodium pentathol
PREPARED BY:	Stella Notzon, DIOP, 301-594-3851

DATE
PUBLISHED: October 27, 2010

Under the Authority of
Domenic J. Veneziano, CDR USPHS

Exh. C

Dohm, Julie

From: Bernstein, Ilisa
Sent: Friday, April 15, 2011 12:08 PM
To: Dohm, Julie
Subject: FW: assistance on sodium thiopental question raised by UK Embassy
Attachments: 101101deathpenaltyletter.doc

From: Abbaszadeh, Nima [mailto:AbbaszadehN@state.gov]
Sent: Thursday, November 04, 2010 2:52 PM
To: Bernstein, Ilisa
Subject: assistance on sodium thiopental question raised by UK Embassy

Ilisa,

I'm writing to you from the UK desk at the State Department at the suggestion of Susie Boggess. I appreciate that you're probably not the right contact for this question, but we're hoping you can point us in the right direction. The attached letter from the British Embassy was sent to our Deputy Assistant Secretary yesterday complaining about the import of sodium thiopental from the UK for use in lethal injections in the United States. The letter claims that UK-sourced sodium thiopental is not FDA-approved. This issue has also received some prominent press attention in the UK (link to article below). I understand a lawsuit has now been filed in London to prevent the drug from being exported to the United States.

At this point, we're just trying to find the appropriate POC at FDA, including someone who can verify the letter's claim that "that Sodium Thiopental sourced from the UK is not FDA-approved for use in the U.S." Any suggestions for who we should be talking to would be greatly appreciated.

http://www.guardian.co.uk/world/2010/nov/02/death-penalty-campaigners-execution-drug

Thanks very much,
Nima

Nima Abbaszadeh
U.K. Desk Officer
U.S. Department of State
Tel: (202) 647-5674
AbbaszadehN@state.gov

This email is UNCLASSIFIED.

British Embassy
Washington

Foreign and Security Policy Group
British Embassy
3100 Massachusetts Ave NW
Washington, DC 20008

Tel: +1 202 588 6524
Fax: +1 202 588 7870
Email: ian.bond@fco.gov.uk
www.ukinusa.fco.gov.uk

Elizabeth L Dibble
Deputy Assistant Secretary of State
Bureau of European and Eurasian Affairs
Department of State

08 April 2011

Dear DAS Dibble

DEATH PENALTY – IMPORT OF SODIUM THIOPENTAL FROM THE UK

As you know, the UK firmly opposes the death penalty in all circumstances as a matter of principle. I am aware that the UK and US governments do not see eye to eye on this. It is nonetheless deeply concerning to hear reports that US States may be importing Sodium Thiopental (a drug which has legitimate therapeutic uses but can also be used in executions) from the UK in order to put convicted persons to death. This follows problems in obtaining this substance from the sole US manufacturer, Hospira, a company which has in the past made clear that it does not support the use of any of its products in capital punishment procedures.

We were especially dismayed to hear about the execution of Jeffrey Landrigan in Arizona on 26 October, given reports that he suffered from severe mental health problems; the 9th US Circuit Court of Appeals had previously stayed his execution because of the lack of clarity about the provenance of the Sodium Thiopental to be used.

We are also very concerned about the possibility of UK drugs being used in future executions in the US, such as the case of Edmund Zagorski in Tennessee. Our understanding is that Sodium Thiopental sourced from the UK is not FDA-approved for use in the US. We would therefore be grateful for any steps the Federal Government can take to prevent it being used here , especially in order to harm rather than heal.

Yours sincerely

Ian Bond

Ian Bond
Political Counsellor

Exh. 7

Dohm, Julie

From: Clare.Bloomfield@fco.gov.uk
Sent: Thursday, November 04, 2010 4:06 PM
To: Lumpkin, Murray
Subject: UK request for information on sodium thiopental

Dear Mr Lumpkin,

With apologies for contacting you out of the blue, I am writing with a request from one of my colleagues in London, Tom Smith, Head of our Export Controls Organisation (part of the Department of Business, Innovation and Skills).

Tom is currently involved in a legal case in the UK revolving around a UK company supplying sodium thiopental to the US, which was then subsequently used for carrying out the death penalty. He is trying to find someone on good authority in the FDA who will be able to answer a question on US general usage of the drug. I believe he thinks it is licensed for use here but is more interested in knowing whether it is in general use.

Sadly this is not my area of expertise but know Tom well which is why he came to me to see if I could help point him in the right direction.

I wonder if it would be ok for me to pass on your contact details and ask him to get in touch with you directly (or one of your colleagues), in order to help him supply an answer to Secretary of State for Business by the end of the week?

I look forward to hearing from you,
Clare

Clare Bloomfield *| Foreign and Security Policy Group | British Embassy | 3100 Massachusetts Avenue NW | Washington DC 20008 |*

Email: Clare.Bloomfield@fco.gov.uk | Tel: (202) 588 6998 | Cell: (202) 213 8460 | FTN: 8430 6998 | www.ukinusa.fco.gov.uk

Help save paper - do you need to print this email?

Dohm, Julie

From: Smith Tom (ITID) [tom.smith@bis.gsi.gov.uk]
Sent: Friday, November 05, 2010 11:27 AM
To: Lumpkin, Murray
Cc: Jenkins Russell (ITID); Martinez-Soto Jose (LEGAL B); Chew Christopher (ITID); Clare.Bloomfield@fco.gsi.gov.uk
Subject: Sodium Thiopental
Follow Up Flag: Follow up
Flag Status: Red

Dear Mr Lumpkin,

Thank you very much for speaking to me just now.

To confirm, we are interested in obtaining an authoritative view from the FDA on the current usage of sodium thiopental for medical reasons within the United States. I note your comment that it is an old drug and that new drugs have since come onto the market. The question is whether, nevertheless

a) it continues to be licensed for use within the US (and, if so, for what purposes);
b) it does in practice continue to be used. Even relatively low levels of usage (as a percentage of anaesthetic procedures) would be relevant information to us.

You kindly agreed to seek to find out this information for me from your experts.

If you were able to give me an answer early next week, that would be extremely helpful.

Regards,

Tom Smith
Head, Export Control Organisation
Department for Business, Innovation and Skills
3rd Floor, "Orchard 3", 1 Victoria Street
London SW1H 0ET
Tel: 0207 215 4355
Email: tom.smith@bis.gsi.gov.uk

Ramos, Merly

From: Lumpkin, Murray
Sent: Tuesday, November 16, 2010 2:03 PM
To: 'tom.smith@bis.gsi.gov.uk'
Cc: Sharfstein, JM; Hamburg, Margaret
Subject: Substantive response from US FDA re: Sodium Thiopental

Dear Mr. Smith,

Thank you for your understanding and for your original inquiry. I do now have information that I hope will still be responsive to your time frame.

You asked for the "authoritative view from the FDA on the current usage of sodium thiopental for medical reasons within the United States.". Currently there is no sodium thiopental for sale in the United States, because the domestically manufactured supply has been unavailable for more than a year. There are no approved or permitted foreign sources of sodium thiopental. As a result, there is currently little to no current usage of sodium thiopental for medical reasons.

To your specific questions:

a) The question is whether it continues to be licensed for use within the US (and, if so, for what purposes);

There is no FDA-approved sodium thiopental for human use in the United States. Although the domestically manufactured supply is not approved, the product has been marketed and commercially available without FDA approval pursuant to FDA's Compliance Policy Guide on Marketed Unapproved Drugs. This document is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf.

b) The question is whether it does in practice continue to be used. Even relatively low levels of usage (as a percentage of anaesthetic procedures) would be relevant information to us.

Currently, sodium thiopental's use is very limited due to the shortage described above. When there is no shortage, there is minimal use of sodium thiopental for medical reasons. Experts consulted by FDA have stated that sodium thiopental would be used in well under 5% of patients presenting for a general anesthetic. There is one scenario where the use of sodium thiopental would likely increase: if there were to be another shortage of propofol, an anesthetic agent. If propofol is in shortage, sodium thiopental would most likely find increased use as an induction agent for general anesthesia. Propofol is not currently in shortage in the United States.

Again, I hope this is responsive to your request

Sincerely,

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner
International Programs
US Food and Drug Administration.

----- Original Message -----
From: Smith Tom (ITID) [mailto:tom.smith@bis.gsi.gov.uk]
Sent: Tuesday, November 16, 2010 09:01 AM
To: Lumpkin, Murray
Subject: RE: Apologies: Sodium Thiopental

Dear Mr Lumpkin,

Thank you. I do understand and appreciate your efforts.

Tom Smith
Head, Export Control Organisation
Department for Business, Innovation and Skills
3rd Floor, "Orchard 3", 1 Victoria Street

London SW1H 0ET
Tel: 0207 215 4355
Email: tom.smith@bis.gsi.gov.uk

The Department for Business, Innovation & Skills (BIS) is building a dynamic and competitive UK economy by creating the conditions for business success; promoting innovation, enterprise and science; and giving everyone the skills and opportunities to succeed. To achieve this we will foster world-class universities and promote an open global economy. BIS - Investing in our future

-----Original Message-----
From: Lumpkin, Murray [mailto:Murray.Lumpkin@fda.hhs.gov]
Sent: 16 November 2010 11:45
To: Smith Tom (ITID)
Cc: Sharfstein, JM; Hamburg, Margaret
Subject: Apologies: Sodium Thiopental

Dear Mr Smith,
I am writing today to offer my sincerest apologies that the US FDA has been unable to supply you with the information you requested in time to be of help in your UK exporting agency's trial tomorrow. I know it is now afternoon in London, and your trial starts tomorrow morning (London time). Even checking on an almost daily basis, as of this morning, I still have not received departmental clearance on a communication to you that would be responsive to your request. I know we have been singularly unhelpful, and, for that, I am truly sorry. I do wish we could have been more helpful to you. Again, many sincere apologies.

If I do happen to receive clearance later today our time, I will, of course, send you what is cleared in the hopes it might be of help, even at that late hour.

Best regards,
Murray Lumpkin

Murray M. Lumpkin, MD, MSc
Deputy Commissioner
International Programs
US Food and Drug Administration.

Exh. K

Arizona Department of Corrections

1601 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5497
www.azcorrections.gov

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

November 10, 2010

Deborah M. Autor
Director, Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Ave, Bldg. 51- Room 5270
Silver Spring, Maryland 20993

Re: Entry #574-0251126-5 Thiopental Sodium

Dear Director Autor:

The Arizona Department of Corrections (ADC) has been awaiting, for over two weeks, the inspection and release of chemicals purchased legally from a company located outside of the United States. We have the shipment in proper storage at our Florence, Arizona facility. Other than a message last week advising us to expect a decision by week's end, and a call on November 9, 2010, from Michael Levey (subsequent to repeated unreturned messages) advising a decision would be made at some undetermined point in the future, my staff have not had success in gaining information regarding the justification of the Food and Drug Administration (FDA) in holding this shipment and preventing the release to ADC. This is contrary to the precedent set by the FDA in releasing a prior shipment.

Given that a much larger shipment of this chemical was successfully entered and released with authorization from the United States Customs Department and the FDA, we respectfully request that you expedite the necessary inspection and release. The delay in this matter is wholly inconsistent with the timely and thorough inspection previously conducted on a much larger shipment of this and other chemicals in September. It is ADC's understanding that the FDA's responsibility in this process extends only to the inspection of the shipment to ensure the labeling and contents are consistent with the information on the bill of lading.

In addition to the previous successful processing through your agency, our legal acquisition of these chemicals was scrutinized extensively in the courts, up to and including the Supreme Court

of the United States of America. Clearly, our actions were approved and we were allowed to successfully utilize these chemicals as a result.

I look forward to your timely and positive response as well as your agency's release of this shipment.

Sincerely,

Charles L. Ryan
Director

cc: Charles Flanagan, Deputy Director
Robert Patton, Division Director, Operations
Karyn Klausner, General Counsel
Kent Cattani, Assistant Attorney General, Capital Appeals Section
Michael Levy, Division of New Drugs and Labeling Compliance
Daniel Solis, Director, Imports Operations Branch
Evanguel Strickland, Import Supervisor
David Thomas, DCM FDA Investigations, Phoenix Office

Exh. J

Sodium Thiopental Statement, Key Messages
December 29, 2010

First, we would confirm the shipments are imported on or behalf of state correctional authorities.

Second, we would release the shipments with the following comment:

"FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity, or any other characteristics."

Third, we would use the following key messages and Q and A to respond to inquiries from the news media and other interested parties.

Key Messages

*The U.S. Food and Drug Administration (FDA) is charged by Congress with protecting the public health. Ensuring the safety and effectiveness of pharmaceuticals used for medical purposes is a core part of FDA's mission.

*Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role. FDA does not verify the identity, potency, safety, or effectiveness of substances imported for this purpose. FDA exercises similar enforcement discretion when these drugs are manufactured and purchased within the United States.

*Accordingly, FDA chooses to continue to defer to law enforcement on all matters involving lethal injection, consistent with the U.S. Supreme Court's ruling in Heckler v. Chaney (1985).

Q and A

1.) What has happened so far this year with the imports of sodium thiopental?

In 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law enforcement in the use of substances for lethal injection, which is consistent with the agency's longstanding policy. The agency did not conduct any review of these products for safety, effectiveness or quality.

2.) What has changed?

Two things. In the context of two death penalty cases in the fall of 2010, it was suggested that FDA "approves" the importation of these drugs for use in lethal injections and/or reviews them for safety, effectiveness, and quality. In actuality, the FDA neither approves nor reviews these drugs for use in lethal injections and feels it necessary to clear up any confusion. Also, FDA reviewed its procedures for the importation of sodium thiopental in concert with CBP. The agencies decided that since FDA does not conduct a review of pharmaceuticals intended for lethal injection, FDA will continue to exercise its enforcement discretion and defer to CBP's system for processing importations. The agencies are working together to develop a system for future shipments that avoids any confusion about whether FDA evaluates shipments of drugs intended for lethal injection.

3.) Is the importation of unapproved sodium thiopental for lethal injection illegal?

In deferring to law enforcement on matters involving pharmaceuticals for lethal injection, FDA is exercising enforcement discretion. This approach by the agency was upheld by the Supreme Court in Heckler v. Chaney (1985). Among the reasons cited by the Court for its decision not to review FDA's non-enforcement against lethal injection drugs is that agencies are responsible for prioritizing their enforcement resources to most effectively achieve their statutory missions. Again, FDA similarly defers to law enforcement with respect to transport of these substances within the United States.

4.) What will happen to any shipments that are currently pending?

FDA is releasing these with the comment: "FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity, or any other characteristics."

EXHIBIT C

Dohm, Julie

From: Burgess, Shelly
Sent: Tuesday, January 04, 2011 9:50 AM
To: 'Koppel, Nathan'
Subject: FW: update
Importance: High

Nathan - As discussed, the following is the latest FDA position on sodium thiopental.

The U.S. Food and Drug Administration (FDA) is charged by Congress with protecting the public health. Ensuring the safety and effectiveness of pharmaceuticals used for medical purposes is a core part of FDA's mission.

Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role. FDA does not verify the identity, potency, safety, or effectiveness of substances imported for this purpose. FDA exercises similar enforcement discretion when these drugs are manufactured and purchased within the United States.

Accordingly, FDA chooses to continue to defer to law enforcement on all matters involving lethal injection, consistent with the U.S. Supreme Court's ruling in Heckler v. Chaney (1985).

Following is information that addresses the import of sodium thiopental -

So far this year with the imports of sodium thiopental , inn 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law cnforcement in the use of substances for lethal injection, which is consistent with the agency's longstanding policy. The agency did not conduct any review of these products for safety, effectiveness or quality.

In the context of two death penalty cases in the fall of 2010, it was suggested that FDA "approves" the importation of these drugs for use in lethal injections and/or reviews them for safety, effectiveness, and quality. In actuality, the FDA neither approves nor reviews these drugs for use in lethal injections and feels it necessary to clear up any confusion. Also, FDA reviewed its procedures for the importation of sodium thiopental in concert with CBP. The agencies decided that since FDA does not conduct a review of pharmaceuticals intended for lethal injection, FDA will continue to exercise its enforcement discretion not to review these shipments and allow processing through CBP's automated system for importations. The agencies are working together to develop a system for future shipments that avoids any confusion about whether FDA evaluates shipments of drugs intended for lethal injection.

Is the importation of unapproved sodium thiopental for lethal injection illegal?

In deferring to law enforcement on matters involving pharmaceuticals for lethal injection, FDA is exercising enforcement discretion. This approach by the agency was upheld by the Supreme Court in Heckler v. Chaney (1985). Among the reasons cited by the Court for its decision not to review FDA's non-enforcement against lethal injection drugs is that agencies are responsible for prioritizing their enforcement resources to most effectively achieve their statutory missions. Again, FDA similarly defers to law enforcement with respect to transport of these substances within the United States.

What will happen to any shipments for correctional facilities that are currently pending?

*FDA is releasing these with the comment: "FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity, or any other characteristics."

I will try to find someone to speak with you. I hope this is helpful.

Best,
Shelly

Exh. N

Guidance for handling pending and future shipments of Sodium Thiopenthal

- **Pending shipments** (2 entries recommended for detention; 3 entries with documents requested):

A. 3 entries with documents requested:
- 112-9839758-3 (SWID)
- 574-0251126-5 (LOS-DO)
- M73-0106684-2 (SWID)

Entry Reviewers:

1. Entry reviewers should review the documents provided by the broker to determine if pending lines are destined for correctional facilities.

   a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

   b. If the document review indicates the shipment is going to a correctional facility, assign a Detention Request (DTR) to the line in order to move it to compliance branch.

Compliance Officers:

1. Select Misc Info Recd from the Next Steps (Log Receipt and Response) screen. Enter "entry documents received" in the Remarks field.

2. Select Miscellaneous Correspondence from the Next Steps (Log Receipt and Response) screen. Enter the following in the Narrative field:

   FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics.

3. Select release and immediately print out the Notice of FDA Action.

4. The Notice of FDA Action will be routed to the filer, importer of record, and consignee (if different from the importer).

5. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature.

6. Mail the CORRECTIONAL FACILITY LETTER to the correctional facility only along with the Notice of FDA Action. In instances where the correctional facility is not the importer or consignee, there will be no Notice of FDA Action for the correctional facility; send only the CORRECTIONAL FACILITY LETTER to the correctional facility.

7. A copy of the signed letter, the Notice of FDA Action, and the entry documentation will be kept in the district's files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the entry reviewer determines that any shipment of sodium thiopental is not destined for a correctional facility, per #1a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the Compliance Officer and will send a copy of the case file, including OASIS screen shots for the entry.

B. <u>2 current entries that have been recommended for detention:</u>
- 112-9673446-4 (NOL-DO)
- 112-9938358-2 (NOL-DO)

Compliance Officers:

1. Request documents from the broker to determine if pending lines are destined for correctional facilities, if not already done by Investigations Branch (IB).

2. Review documents submitted by broker or IB to determine if pending lines are destined for correctional facilities.

   a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

b. If the document review indicates the shipment is going to a correctional facility, the Compliance Officer will:

i. Select Misc Info Recd from the Next Steps (Log Receipt and Response) screen. Enter "entry documents received" in the Remarks field.

ii. Select Miscellaneous Correspondence from the Next Steps (Log Receipt and Response) screen. Enter the following in the Narrative field:

FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics.

3. Select release and immediately print out the Notice of FDA Action.

4. The Notice of FDA Action will be routed to the filer, importer of record, and consignee (if different from the importer).

5. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature.

6. Mail the CORRECTIONAL FACILITY LETTER to the correctional facility only along with the Notice of FDA Action. In instances where the correctional facility is not the importer or consignee, there will be no Notice of FDA Action for the correctional facility; send only the CORRECTIONAL FACILITY LETTER to the correctional facility.

7. A copy of the signed letter, the Notice of FDA Action, and the entry documentation will be kept in the district's files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the shipment of sodium thiopental is not destined for a correctional facility, per #1a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the Compliance Officer and will send a copy of the case file, including OASIS screen shots for the entry.

➢ **Future entries effective January 5, 2011:**

DIOP Systems Branch:

1. Criteria will be placed in OASIS and MARCS ER to flag all shipments of Sodium Thiopental as a priority review.

Entry Reviewers:

1. When an entry of sodium thiopental is identified, do not search the agency's databases to verify manufactures registration and listing information or the approval status of the drug.

2. Request documents from the broker to determine if the line(s) are destined for correctional facilities.

3. Review documents submitted by broker to determine if pending lines are destined for correctional facilities.

   a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

   b. If the document review illustrates that it is going to a correctional facility, the Entry Reviewer will select May Proceed and enter the following narrative when prompted:

      "FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics"

4. Take a screen shot (print screen) of the language documented in the "Remarks" section. This document will be forwarded to DIOP as part of the HQ notification process.

5. The line will then be "May Proceeded".

6. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature. Mail the letter to the correctional facility only.

7. A copy of the signed letter, the "Remarks" screen shot, and the entry documentation will be kept in the districts files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the shipment of sodium thiopental is not destined for a correctional facility, per #3a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the District and will send a copy of the case file, including OASIS screen shots for the entry.

Additional actions that need to be completed:

1. Compliance Policy Guide needs to be written.

2. Conference call needs to be set up to notify import staff across the organization on the new guidance and answer questions that they may have.

3. Reports will be generated and used to assure that guidance is being followed uniformly and consistently across ORA and feedback provided in accordance with QMS policies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

[DISTRICT LETTERHEAD]

CORRECTIONAL FACILITY LETTER template

[CORRECTIONAL FACILITY NAME & ADDRESS]

This letter provides the status of entry # XXX-XXXXX-X, which consists of [AMOUNT] of [PRODUCT DESCRIPTION]. FDA received documentation for this shipment and verified it is destined for a state correctional facility.

FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics

Sincerely,

[DISTRICT DIRECTOR SIGNATURE BLOCK]

Exh. O

Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/24/2009	**Inspection Start Date:** 07/08/2009		**Inspection End Date:** 07/08/2009
Firm Name & Address:	Sandoz GmbH , Biochemiestrasse 10 Kundl		
Firm Mailing Address:	Bachmann Strasse 7, Kundl ,1234, Austria		
FEI: 3002806523	**JD/TA:**	**County:**	**Est Size:** 50,000,000 - and over
Phone:		**District:** IOG	**Profiled:** Yes
Conveyance Type:	**% Interstate:** 100	**Inspectional Responsibility:**	

Endorsement

This GMP inspection of the firm Kundl, Austria laboratory facilities was conducted concurrently with an inspection of the firms heparin USP manufacturing site in Schaftenau, Austria. This inspection was performed in accordance with CP 7356.002F, Active Pharmaceutical Ingredient Inspection and CP 7346.832 Drug Process Inspection. The was a limited systems inspection focused on the heparin API analysis. The cinspection covered in limitied aspects included Quality Assurance and Control, including Laboratory and Materials, and Facilities/Equipment systems. It was conducted as per the request of the CDER International Compliance Branch and Division of Field Investigations, International Operations Branch, (Trip No. 2009-116D).

The previous FDA inspection of this facility in Kundl, Austria was conducted in 2008 and was classified VAI. The purpose of that inspection was to conduct a pre-approval and general GMP inspection of Amoxicillin; Clavulanate Potassium (ANDA 90-227) and Cefpodoxime Proxetil (ANDA 90-031). Four observations were noted on a FDA Form 483 regarding raw material/component conformity testing, reserve sample selection, identity of drug product testing and component receipt procedures. Corrections made to the observations were verified during this inspection.

This inspection focused on the quality assurance and control of the following:
Heparin Sodium, USP for Enoxaparin Sodium API, DMF 18557; the applicant is Sandoz (USA)

During this inspection, no observations were noted on a FDA Form 483.
Please see separate memo generted by the OGD reviewer on the inspection. Memo dated 7/20/2009
o=CDER International Compliance Branch
F/U: concur with approval based on facility inspection

Endorsement Location: Turbo/DFI

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Kevin P Foley	01/13/2010 03:16 PM ET	Susan F Laska	01/13/2010 06:07 PM ET
Kevin P Foley	08/06/2009 04:49 PM ET		ET

Establishment Inspection Report	GGD/SMJ	FEI:	**3002806523**
Sandoz GmbH		EI Start:	07/19/2010
Kundl, Austria		EI End:	07/29/2010

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SUMMARY

(written by GGD)

This inspection was a routine GMP inspection conducted in accordance with the Compliance Programs (CPs) 7356.002, "Drug Process Inspections," 7356.002A, "Sterile Drug Process Inspections," 7356.002M, "Inspections of Licensed Therapeutic Drug Products," and 7356.002F, "Bulk Pharmaceutical Chemicals," and the Guidance for Industry Q7A, Good Manufacturing Practice Guidance for APIs. The most recent inspection of this firm was a directed inspection covering the quality control and quality assurance operations specific to Heparin Sodium USP. The inspection was conducted 06Jul – 10Jul2009 concurrently with the inspection of the Sandoz manufacturing facility in Schaftenau, Austria. Heparin Sodium USP is manufactured as described in the Drug Master File (DMF) 18557, at the Schaftenau site and is tested at this site in Kundl Austria. No FDA 483, Inspectional Observations, was issued at the conclusion of the prior inspection and no deficiencies were noted. The inspection was classified as No Action Indicated (NAI).

Establishment Inspection Report	GGD/SMJ	FEI:	**3002806523**
Sandoz GmbH		EI Start:	07/19/2010
Kundl, Austria		EI End:	07/29/2010

The current inspection was requested by the International Operations Branch, (HFC-130), to conduct a full GMP inspection covering the manufacturing processes for products shipped to the United States. The inspection was accomplished under FACTS Assignment ID # 1161698.

Sandoz GmbH (Kundl Austria) continues to manufacture sterile and non-sterile finished dosage form pharmaceutical and biopharmaceutical products, and sterile and non-sterile active pharmaceutical and biopharmaceutical ingredients. The products include cephalosporins, penicillins, and [redacted] products. The profile classes for U.S. marketed products include SVS (aseptically processed small volume parenterals), LVP (large volume parenterals); POW (powders, includes non-sterile oral and topical); TCM (tablets – prompt release); TCT (tablets – delayed release); TTR (tablets – extended release); CHG (capsules – prompt release); CCS (chemical synthesis crude); CFN (non-sterile bulk by fermentation crude drug); CFS (sterile bulk by fermentation crude drug); CSN (non-sterile bulk by chemical synthesis crude); CSS (sterile bulk by chemical synthesis crude); and CBI (Biotechnology Crude).

The inspection was conducted concurrently with the inspection at the Sandoz GmbH site in Langkampfen, Austria, referred to as the Schaftenau site. Sandoz GmbH, Schaftenau also manufactures sterile and non-sterile finished dosage form pharmaceutical/biopharmaceutical products and active pharmaceutical/biopharmaceutical ingredients. All release and stability testing for products manufactured at the Schaftenau site is performed by at the Sandoz GmbH Kundl site. In light of the types of products and profiles classes, the time allotted for this inspection at both sites was insufficient to conduct a comprehensive cGMP inspection covering all profile classes. Five days was allotted for the inspection at the Kundl site and 4 days was allotted for the inspection at the Schaftenau site.

The current inspection at the Kundl site evaluated the quality, production, and laboratory-control systems, and to a limited extent the facilities-and-equipment, and packaging-and-labeling systems. Several deficiencies were noted and were listed on a FDA-483, Inspectional Observations, issued at the conclusion of the inspection to Mr. Ernst Meijnders, Chief Executive Officer and Head of Business Unit Anti-Infectives & API.

The deficiencies and recommendations noted during the inspection pertained to investigations and documentation of unusual events/occurrences; the personnel monitoring program and gowning practices; [redacted] sterilization of equipment and supplies in the [redacted] equipment cleaning and use logs; and the containment program. They included the following.

- The investigation related to the sterility failure of [redacted] was poorly documented in that it did not include an evaluation of [redacted] which was aseptically filled on the same day (09Apr2009) prior to [redacted]. The filling equipment/line was not dismantled and cleaned/sterilized between batches [redacted] and [redacted]. Sterile [redacted] products are aseptically filled on a campaign basis which consists of up to [redacted] fill days. One of the possible causes of the sterility failure was attributed to a change of the

transport belts in the filling machine during the fill of [redacted]; however, this was performed successfully during a subsequent media fill. A second possible cause of the failure was a mix up of the vials sampled for sterility samples and machine adjustment vials after replacement of the belt. However, this could not conclusively be shown and product in the machine adjustment vials should be sterile. Additionally, environmental monitoring data collected during both fills including settling plates which are exposed on the fill line though out the aseptic fill revealed no problems. Only batch [redacted] was rejected.

- Procedure 07.070 "Aseptic Filling of [redacted]" was found deficient in that the change of a transport belt during an aseptic fill, which requires clearing the line of all vials, is not identified as a critical event. As such it would not be recorded in the production record documentation. Additionally, the procedure does not require operators to document unusual events at the time of occurrence. For example, during the aseptic fill of [redacted], vials were falling over and problems were experienced with the transport belt, which had to be replaced. These occurrences were not recorded in the batch production record.

- Personnel responsible for cleaning the grade [redacted] areas in the aseptic processing areas (including fill rooms) are not monitored except during their [redacted] requalification. [redacted] the cleaning personnel gown in sterile garb and enter the aseptic filling room to clean the grade [redacted] areas outside the filling line while production activities are ongoing.

- The actual number of materials and equipment sterilized in the [redacted] for each individual [redacted] run/load are not documented to ensure that the maximum load established during validation is not exceeded.

- The sterile face mask and hood worn during aseptic filling operations does not always provide sufficient coverage. On 19Jul2010, during the aseptic fill of [redacted] batch [redacted], exposed skin was observed between the face mask and the hood of two aseptic filling operators caused by an inadequate fit of the mask. On 20Jul2010, this was again observed during the demonstration of the gowning procedure.

- Equipment cleaning and use logs are inadequate in that the product name, batch number, and cleaning times are not routinely recorded.

- The containment program does not include an adequate evaluation of personnel movement between the [redacted] production plants in that personnel are not periodically monitored and personnel are not restricted from moving between the buildings where [redacted] products are manufactured.

In addition, several deficiencies and/or recommendations were presented verbally during the close-out discussion. They included the following.

- The interventions during the worst case media fills for lines [redacted] and [redacted] do not adequately reflect the interventions during the fill. [redacted] bags of [redacted] are manually added to the hopper on the filling line per batch. However, only [redacted] additions are simulated during a media fill. This concern was noted late in the inspection and as such was discussed verbally with management.

- Smoke studies to evaluate air flow patterns in the Grade [redacted] areas outside the aseptic filling lines appear outdated in that they were performed with minimal equipment and supplies in the fill rooms. Currently a large rack with 7 to 8 shelves packed full of sterile equipment and supplies, trolleys [redacted] with canisters containing sterile [redacted] the [redacted] conveyor/cart, the table containing the weigh area for the canisters and/or bags of product, a step ladder, and a chair, etc., are routinely located in the filling rooms during production activities.

- Not all aseptic fill lines are equipped with timers to ensure that personnel performing the [redacted] control are changed after [redacted] as required in procedure 02.016.

- Personnel working in controlled (Grade [redacted] areas and non-sterile production areas are not required to wear socks.

Firm management corrected many of the deficiencies/recommendations prior to completion of the inspection and stated they would respond in writing to the observations.

ADMINISTRATIVE DATA

Inspected firm:	Sandoz GmbH
Location:	Biochemiestrasse 10 Kundl, Austria
Phone:	+43 (0) 5338 200 3400
FAX:	+43 (0) 5338 200 3650
Mailing address:	Biochemiestrasse 10 6250 Kundl, Austria
Dates of inspection:	7/19/2010, 7/20/2010, 7/21/2010, 7/22/2010, 7/23/2010, 7/27/2010, 7/29/2010
Days in the facility:	7
Participants:	Gwyn G. Dickinson, Investigator Susan M. Jackson, Microbiologist

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, CDER/OC/DMPQ/ICT, HFD-325 10903 New Hampshire Avenue, Building 51, Room 4218 Silver Spring, Maryland 20993 USA Tel. No. 301 796-3334, Fax No. 301 847-8738	July 19-23, 27, & 29, 2010 FEI NUMBER 3002806523

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ernst Meijnders, Head of Business Unit Anti-Infectives & API, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Sandoz GmbH	Biochemiestrasse 10
CITY, STATE AND ZIP CODE 6250 Kundl, Austria	TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer (Finished Dose & API)

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. The investigation related to the sterility failure of [redacted] (b)(4) batch [redacted] (b)(4) was poorly documented in that it did not include an evaluation of [redacted] (b)(4), batch [redacted] (b)(4) which was aseptically filled on the same day (09Apr2009) prior to [redacted] (b)(4).

2. Procedure 07.070 "Aseptic Filling of [redacted] (b)(4)" is deficient in that the change of a transport belt during an aseptic fill, which requires clearing the line of all vials, is not identified as a critical event. As such it would not be recorded in the production record documentation. Additionally, the procedure does not require operators to document unusual events at the time of occurrence. For example, during the aseptic fill of [redacted] (b)(4), batch [redacted] (b)(4), vials were falling over and problems were experienced with the transport belt, which had to be replaced. These occurrences were not recorded in the batch production record.

3. Personnel responsible for cleaning the grade [redacted] (b)(4) and [redacted] (b)(4) areas in the aseptic processing areas (including fill rooms) are not monitored except during their [redacted] (b)(4) requalification.

4. The actual number of materials and equipment sterilized in the [redacted] (b)(4) for each individual [redacted] (b)(4) run/load are not documented to ensure that the maximum load established during validation is not exceeded.

5. Equipment cleaning and use logs are inadequate in that the product name, batch number, and cleaning times are not routinely recorded.

6. On 19Jul2010, during the aseptic fill of [redacted] (b)(4), batch [redacted] (b)(4), exposed skin was observed between the face mask and the hood of two filling operators caused by an inadequate fit of the mask. On 20Jul2010, this was again observed during the demonstration of the gowning procedure.

7. The Cross Contamination Protection program does not include an adequate evaluation of personnel movement between the [redacted] (b)(4) and [redacted] (b)(4) production plants in that personnel are not periodically monitored.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Gwyn C. Dickinson Susan M. Jackson	Gwyn C. Dickinson, Investigator Susan M. Jackson, Microbiologist	July 29, 2010

ACLU
AMERICAN CIVIL LIBERTIES UNION of

GUARDIAN
THE SAN FRANCISCO BAY GUARDIAN

July 8, 2011

Deputy Assistant Secretary for Public Affairs (Media)
U.S. Department of Health and Human Services
7700 Wisconsin Ave., Suite 920
Bethesda, MD 20857

Re: FOIA Appeal, Reference # 2011-319 and 2011-3905

Dear Deputy Assistant Secretary:

Requestors American Civil Liberties Union of Northern California (ACLU-NC) and the *San Francisco Bay Guardian* (*Guardian*) write to appeal the Food and Drug Administration's (FDA) decision not to provide us with the information we requested under the Freedom of Information Act (FOIA), identified by the FDA as FOIA Request # 2011-319 (the "Request"). Specifically, with this letter, we appeal the continued refusal to fully release information from the Los Angeles District Office of the Food and Drug Administration ("LA District Office"), Request # 2011-3905.[1]

On January 4, 2011, we requested records pertaining to the acquisition of controlled substances by state officials for the purpose of carrying out executions of condemned prisoners by lethal injection. In our request, ACLU-NC and *Guardian* sought the release of twelve categories of information pertaining to the importation, transfer, or purchase of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution. *See* Exh. A (FOIA Request dated January 4, 2011). On March 31, 2011, requestors received 35 pages of records from the LA District Office, accompanied by a letter from Analyst John Bryce (the March 31 documents). See Exh. B (Response to FOIA Request from John Bryce dated March 31, 2011). On April 29, 2011, requestors filed a request for reconsideration, seeking release of certain redacted information in the March 31 documents and release of additional documents. See Exh. C. The LA District Office partially granted our request and on June 10, 2011, we received 41 pages of records from the LA District Office (the June documents) with

[1] Requestors have already lodged an appeal with FDA regarding redactions made to other disclosed documents released by the FDA in response to FOIA Request # 2011-319 and regarding the agencies failure to conduct a comprehensive search for records, Appeal # 2011-2661. The current appeal should be considered with Appeal # 2011-2661.

AMERICAN CIVIL LIBERTIES UNION OF NORTHERN CALIFORNIA
39 DRUMM STREET, SAN FRANCISCO, CA 94111 | T/415.621.2493 | F/415.255.1478 | TTY/415.863.7832 | WWW.ACLUNC.ORG

fewer redactions. Exh. D. However, critical information that the public has a right to see continues to be withheld.

We write to appeal the agency's decision to withhold the redacted information and the failure to release all relevant documents in the agency's possession, pursuant to 45 C.F.R. § 5.34. We believe the FOIA exemptions cited by the FDA do not apply to the records we requested. We further believe that the agency has failed to adequately search for responsive records and that additional records are in the agency's possession that should be released.

We incorporate by reference our previous letters to the FDA dated February 15, 2011 (the February 15 letter) (attached as Exhibit E) and April 29, 2011 (attached as Exhibit C), which further explain our objections to the redactions.

Redactions Pursuant to 5 U.S.C. § 552(b)

The redactions to the June 10 documents appear to rely on the following sections of the FOIA Statute:

- 5 U.S.C. § 552(b)(4), trade secret and confidential commercial information;
- 5 U.S.C. § 552(b)(5), certain interagency and intra-agency communications; and
- 5 U.S.C. § 552(b)(6), information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy.

The FDA relies on the (b)(4) exemption primarily as authority to redact the price and quantity of imported sodium thiopental. The FDA also relies upon (b)(4) in redacting transportation information such as flight numbers, carrier and receiving party addresses. As we explained in our February 15 and April 29 letters, such price, quantity and transportation information is not confidential commercial or financial information, nor is it a trade secret. *See* Exhs. E and C.

The FDA also cites (b)(6) to redact the names of applicants who request delivery of sodium thiopental, pancuronium bromide, and/or potassium chloride as well as the names and addresses of the senders or receivers of such drugs. Exh. D. It is difficult to see how such information is "about individuals in personnel, medical and similar files." Furthermore, releasing these names and addresses would hardly constitute "an unwarranted invasion of personal privacy." In fact, the e-mails that the FDA released contain the names of FDA and Arizona Department of Corrections personnel who seemed to be the applicants, senders and receivers of these drugs. For example, in an e-mail sent by Thomas David of the FDA, he stated: "Mr. Charles Flanagan, Deputy Director Arizona Department of Corrections (602) 542-3611 contacted CSO David Thomas from the FDA office in Phoenix stating he wanted to import a shipment of drugs from overseas and asked the procedures." Exh. D. The FDA's inconsistent applications of the (b)(6) exemption within this release document also demonstrates that the FDA has incorrectly applied the (b)(6) exemption.

Lastly, while Requestors cannot determine the content that has been redacted based on Exemption (b)(5), because of the incorrect usage of the other exemptions, we ask for reconsideration of this redaction as well.

Unreleased Records

We requested the release of the Entry and Manifest form of the shipment with Entry Number 574-0251126-5 in our April 29 Appeal, a document that should be within the possession of the LA District Office. Exh. C. The FDA still has not released the requested form in the newly released, less redacted document. Exh. D. We hereby incorporate our argument in the April 29 Appeal and request the FDA to release the requested form or inform the requester the reason for the withholding. Exh. C.

* * *

For the foregoing reasons, we respectfully appeal the FDA's refusal to release the requested information and failure to disclose all relevant records. We look forward to your prompt response.

Sincerely,

Natasha Minsker
Death Penalty Policy Director, ACLU-NC

Also on behalf of Tim Redmond
Executive Editor, *San Francisco Bay Guardian*